EXHIBIT 2

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DECLARATION OF JAMES P. MITTENTHAL

James P. Mittenthal declares and says:

I. BACKGROUND

1. My name is James Peter Mittenthal. I am over twenty-one years of age and of sound mind. I am competent to affirm all of the matters set out in this Declaration.

2. I am currently employed as the Vice President of Consulting Services at Epiq Systems, Inc., eDiscovery and Litigation Solutions. Previously, from 1985 through 1992, at Legal Support Services Corporation, I developed a suite of law office software and other technology to manage large-scale document productions in product liability and other mass litigation. In 1992, I joined Price Waterhouse, where I spent four years advising law firms and law departments regarding information technology and information management issues, including issues regarding record retention and the discovery life cycle. In 1995, I opened the New York office of Baker Robbins & Company, a national technology consulting firm. Through 16 years at the firm (including its acquisition by Thomson Reuters and merger with Hildebrandt International), I assisted law firms and law departments with technology acquisition, information management, and litigation support, and eventually headed its litigation support group, before

our group transitioned the practice to Epiq in 2011. I hold a bachelor's degree in English (Honors Program) from the University of Michigan and a law degree from Boston University.

3. Over the last 28 years supporting the legal services industry, I have had extensive experience advising corporations, governmental entities, and other organizations regarding user-created information, enterprise and departmental information, archival information, and the supporting infrastructure; retention and disposition of business information and records, both in the ordinary course of business and in connection with litigation, including the implementation of appropriate legal holds; and the assessment, collection, and production of hard copy and electronically stored information in litigation.

II. OVERVIEW OF WORK ON BEHALF OF ETHICON

4. Beginning in or about August 2011, I was asked by Ethicon, Inc. ("Ethicon") to examine the company's efforts with respect to records management and retention and its underlying technology environment, among other topics, to prepare for and provide testimony as a corporate representative in connection with the pelvic mesh litigation in the MDL and New Jersey cases.

5. In connection with my review, I interviewed over 100 different individuals, sometimes on multiple occasions, in connection with network infrastructure, business systems, and records management and retention, including both Ethicon and Johnson & Johnson personnel within Information Technology, Quality Systems, Supply Chain, Regulatory, Research and Development, Marketing, and Sales groups, as well as certain third parties with information and facilities management or collection responsibilities. At least 50 of my interviews were mainly concerned with records management and retention.

6. In addition, I conducted numerous onsite visits to Ethicon's headquarters in Somerville, New Jersey, as well as to the corporate data center and offices in Raritan, New Jersey and the Health Care Systems facilities in Piscataway, New Jersey.

7. In approximately April 2013, I was asked to examine certain record retention issues related to specific custodians who had been found to have few or no documents in their "custodial files." In this context, I spoke to current employees and former employees, including managers, administrative assistants, as well as records management, information technology and human resources personnel. In connection with this aspect of my work, I also requested, received, and reviewed portions of deposition testimony of certain former employees and documents regarding compliance with records retention procedures, such as completed exit checklists.

8. As part of my work, I have provided deposition testimony as a corporate representative on behalf of Ethicon on five different occasions: December 7, 2011; December 4, 2012; May 14, 2013; August 13, 2013; and September 25, 2013. Plaintiffs devoted the last three days of deposition primarily to records retention and the issue before this Court.

III. SUMMARY OF FINDINGS

9. The following is a summary of my key findings, which are set out more fully below:

- Ethicon has produced millions of pages of documents in this litigation, which include design and development, regulatory, marketing, complaints and clinical data documents collected from central sources as well as hundreds of individual custodians working in these functional areas.

- At all time periods relevant to this litigation, Ethicon has had in place written record retention policies, procedures, training, and technology that were reasonably designed to effectuate record retention consistent with its obligations both in the ordinary course of business and in connection with pelvic mesh litigation.

- Beginning in approximately April 2013, Ethicon identified that certain former employees' "custodial files" contained few or no documents. I determined that, in many cases, the employee understood and properly preserved documents while working at Ethicon, but upon the employee's departure or separation from the company, his or her electronic data were not properly transferred to the company due to miscommunication or misunderstanding.

- Both in the normal course and in direct response to the identification of these issues, Ethicon has taken – and continues to take – steps to address them (as well as its record retention and legal hold practices in general) and implement processes to minimize the risk of similar losses of data in the future.

- The impact of the loss of any individual-level data is minimized in light of the following:

    - the modern corporate environment, in which technology infrastructure directs users to create and manage documents and information in centrally stored and managed locations, such as Microsoft SharePoint sites, group or department shares, databases, and other electronic systems, rather than on a drive to which only a single user has access; and

    - the redundancies incorporated into Ethicon's document collection practices (collection from databases and other central sources and collection from numerous custodians within a single functional area).

- At no time during my examination and assessment did I identify any instance in which Ethicon intentionally or selectively destroyed materials known to be relevant to the pelvic mesh litigation.

IV. ETHICON'S DOCUMENT COLLECTION AND PRODUCTION TO DATE HAVE BEEN FAR-REACHING AND SUBSTANTIAL

10. I understand that, as of December 1, 2013, Ethicon has produced more than 1.5 million documents, comprising more than 10.5 million pages, in connection with this pelvic mesh MDL. Further, Ethicon has produced millions of additional pages of documents in native form.

11. Ethicon collected these documents from a wide range of electronic and paper sources both in and outside the United States. They include both custodial (individual) and non-custodial (general or central) sources.

12. Ethicon's custodial collections took into account more than 250 current or former internal employees who held responsibilities in a wide variety of areas pertaining to Ethicon's pelvic mesh products, including research and development; design and engineering; preclinical testing; clinical development; regulatory; manufacturing; quality and compliance; labeling; marketing; sales; professional education; medical affairs; and post-market surveillance. In addition, I understand that document collections have been performed for more than 150 current and former sales representatives of Ethicon.

13. Typically, Ethicon performed custodial collections for multiple individuals in a department or area. For example, in some areas, such as marketing, more than 35 individuals were the subject of custodial collections. Likewise, Ethicon collected from more than 20 individuals employed in a clinical or medical affairs capacity and more than 15 individuals who had regulatory responsibilities.

14. In addition, significant volumes of electronic and hard copy documents have been collected from non-custodial sources such as group and departmental file shares, databases, websites, other enterprise electronic systems, and warehouse storage facilities.

15. These materials collected from general or central sources encompass the same broad range of subject matters or functional areas identified in paragraph 12 above, including design, regulatory, labeling, copy review (which includes marketing, professional education and training), clinical and preclinical studies, and complaints.

16. Most "files of record" (many of which are required to be maintained and preserved by Ethicon under federal and other regulations) are maintained in general or central sources, rather than in any one individual's custody.

a. For example, the Design History File, or DHF, is a collection of materials that Ethicon maintains centrally. The DHF memorializes the design and development of a given product. It comprises a vast array of materials, including design drawings, testing reports, meeting minutes, memoranda, and emails. A DHF for a single product may number tens of thousands of pages. Ethicon has produced the DHF for each of the 15 pelvic mesh products at issue in this MDL.

b. Likewise, Ethicon's applications for 510(k) regulatory clearance for its products are document collections that are maintained centrally. Ethicon has collected and produced the 510(k) application files for each of the pelvic mesh products at issue in this MDL, which include the applications and supporting materials as well as correspondence to and from FDA.

c. Ethicon has collected and produced Instructions for Use (IFUs), which were included in the packaging of the product, for each of the pelvic mesh products at issue in this MDL. The IFUs and other labeling materials were collected from the AGILE database, a document control application.

d. Ethicon's copy review of marketing and certain training and professional education materials is conducted on a centrally-maintained electronic database, Blue. Relevant materials from Blue have been collected and produced in this litigation.

e. Federal regulations require Ethicon to maintain files regarding all reports of complaints or adverse events associated with the products it manufactures. Ethicon maintains its complaint files on enterprise systems,

and is producing in this litigation complaint files regarding the pelvic mesh products at issue, regardless of the country from which the complaint originated.

f. Ethicon manages information pertaining to clinical research regarding the pelvic mesh products in various Microsoft SharePoint sites, network shares, and the Oracle Clinical database. Each of these central sources has been subject to collection and production.

V. ETHICON HAS ESTABLISHED SOUND GENERAL RECORD RETENTION POLICIES AND PROCEDURES AND HAS ISSUED TIMELY AND APPROPRIATE HOLD NOTICES IN PELVIC MESH LITIGATION

17. My fact-finding shows that, at all times relevant to this litigation, Ethicon has had in place written record retention policies, procedures, training, and technologies that were reasonable for a company of its type and size and were designed to facilitate appropriate record retention, both in the ordinary course of its business operations and regulatory framework generally and in connection with pelvic mesh litigation specifically.

Ethicon's Ordinary Course Record Retention

18. By way of background, Ethicon employs more than 11,000 people worldwide and has offices, Research & Development centers, and manufacturing facilities in more than 50 countries.

19. As a medical device manufacturer, Ethicon operates in the ordinary course of its business in a highly regulated environment, including with respect to record retention.

20. To comply with its regulatory requirements with respect to record retention, Ethicon has established robust policies, schedules, and procedures governing retention that apply even in the absence of litigation.

21. These policies, schedules, and procedures, which I understand are described more fully in the declaration of Lisa Kaiser, Ethicon's Director of Worldwide Quality Systems, take into account Ethicon's business and operational requirements as well as tax, regulatory, and corporate policy mandates. Ethicon uses a variety of means to drive policy creation, development, and conformity with corporate standards, such as annual audit reviews and the Corrective Action and Preventative Action (CAPA) mechanism.

22. The schedules and procedures provide clear guidance as to how numerous different categories of records and information stored in various formats or "containers" (e.g., paper, electronic) are to be retained. Under Ethicon's ordinary course records retention, many types of records related to its products (including but not limited to pelvic mesh products) are retained for at least the "life of production" (product) or "life of the organization" (Ethicon), including design history files (DHFs), laboratory notebooks, technical reports, labeling content, and FDA submissions.

23. This is not to say, however, that Ethicon or any other company should (or is required to) retain every document for all time.

24. The American Records Management Association (ARMA) and the International Standards Organization (ISO) both provide that, absent a legal, regulatory, historical, or other reason defined in an organization's retention schedule, information should be dispositioned when it no longer has a valid business function or purpose.

25. Ethicon's records retention policies, schedules, and other procedures encompass the above principles, providing overarching reminders that documents should not be retained past their defined retention period unless subject to a hold notice.

26. Ethicon has in place training programs and protocols to educate its employees as to record retention. New employees at Ethicon receive Records and Information Management (RIM) training. An example of a training program from 2011 is attached as Exhibit A.

27. This training provides an overview of the records and information management program, including its benefits and the risks of non-compliance. It provides detailed information regarding other issues such as (i) the lifecycle of records and information; (ii) the distinction between a record and convenience information; (iii) roles and responsibilities with respect to records and information management; (iv) managing electronic records in particular; and (v) legal holds (the last of which will be discussed further in paragraphs 40 to 43 below).

28. Ethicon's training is interactive, requiring employees to "check their understanding" of these issues as they move through the program. Employees are required to re-certify themselves on this training on an annual basis and receive reminder emails if they have not completed the training.

29. In addition to the above "ordinary course of business" practices, Ethicon took specific steps to promote appropriate record retention in connection with the commencement of litigation regarding its pelvic mesh products.

Litigation Hold Notices Issued in Connection with Pelvic Mesh Litigation

30. In April 2008, Ethicon issued to its employees a series of hold notices pertaining to pelvic mesh litigation in New Jersey, and later, in the MDL. Ethicon issued at least 12 litigation hold notices and/or reminders between April 2008 and the present. The most recent notice was sent in July 2013. I understand that another reminder hold notice will be sent shortly.

31. The first several hold notices were product-specific; each notice pertained only to one or two products at issue in a particular individual case or cases. The hold notices issued

since about 2011 have been "omnibus" in nature and address all 15 products that are at issue in this MDL. The progression of these holds is consistent with my understanding of the development of this litigation, which I understand is set forth more fully in the declaration of Benjamin M. Watson.

32. While the language in the hold notices varies slightly from notice to notice, all of the notices reflect a company that takes its retention obligations both seriously and methodically.

33. For example, the April 2008 hold notice unambiguously instructed employees, "**Do not discard, destroy, or alter in any way any**" documents – regardless of type (e.g., paper, electronic, audio/video files) – pertaining to the subject matters identified (original emphasis). It further provided that "**[f]ailure to preserve these materials could result in Court imposed penalties or sanctions on both the company and/or individual employees**" (original emphasis).

34. The litigation hold notices are broad in scope, delineating numerous categories of materials that employees must preserve regarding the products at issue, including documents pertaining to (1) Labeling; (2) Pharmacovigilence/Quality/Post-Market Surveillance; (3) Regulatory; (4) Discovery, Research and Development and Quality Engineering; (5) Product Communications; (6) Marketing and Sales Material; (7) Professional Education; (8) Manufacturing Documents and Equipment; and (9) Medical Affairs and Clinical Studies; and (10) Distribution. (See, e.g., February 18, 2011, hold notice)

35. Taking advantage of technologies that became prevalent between 2007 and 2008, Ethicon established a separate centrally-managed archive repository, which users viewed on their desktops or in their email systems as "litigation hold folders." Employees could move or copy documents into the hold folder to easily retain them for litigation purposes. (With further

advances in technology, particularly with respect to the core mail system, the need for a separate third party repository was eliminated by 2013, as discussed in paragraph 55 below.) These litigation hold folders – as well as directives on how to use them – are described in the hold notices.

36. Ethicon and its corporate parent promoted the well-founded philosophy and practice that an individual is in the best position to understand and manage his or her information and records in the ordinary course of business and under a litigation hold, subject to employee education and oversight. Indeed, in my experience, this is the way the large organizations typically manage their legal holds.

37. Consistent with the above philosophy, use of the litigation hold folders was not mandatory, according to the Records Manager. Rather, Ethicon provided the litigation hold folders to employees as one of several retention vehicles.

38. Thus, individuals were provided the flexibility (and in fact did) manage their information and records in different ways during their employment and at their departure (e.g., using the litigation hold folders, using other folders that are retained, copying materials to a CD) that proved most conducive to business use, while complying with their obligations under Ethicon's litigation hold.

39. Because this was true both during an individual's employment and in connection with his or her departure, it may explain (as discussed further below) why some former employees had no documents attributed to them in a "custodial file."

Education and Training on Legal Holds

40. Ethicon has made an ongoing and conscientious effort to educate its employees as to their responsibilities to preserve information for litigation purposes. In addition to the

guidance regarding compliance contained in the hold notices themselves (including, in some notices, a section addressing "frequently asked questions"), Ethicon has conducted training on the hold notices.

41. As mentioned in the prior section regarding retention in the ordinary course, new employees at Ethicon receive Records and Information Management (RIM) training. This training includes materials specifically directed to developing new employees' understanding document preservation notices.

42. For example, the 2011 training explains what a document preservation or legal hold notice is and how to read it. It then tests the employee's understanding of compliance through an exercise. Finally, the training includes a summary discussion of the legal hold requirements. Employees are also required to complete this legal hold training on an annual basis and receive reminder emails if they have not completed the training.

43. My fact-finding revealed a widespread, albeit uneven, understanding by Ethicon employees of both the existence of pelvic mesh-related litigation hold notices and the substantive requirements of the notices.

Other Procedures Affecting Record Retention

44. Two other procedures are pertinent to Ethicon's compliance with the retention policies and litigation hold notices discussed above.

45. Ethicon's "North America Process Specification for Onsite Paper/Electronic Clean-up (PS-0000117)" outlines an annual systematic process for reviewing all paper and electronic company records. It provides a records review checklist to determine each document's disposition. The first item on the checklist instructs employees to preserve the document if it has to be retained for litigation.

46. Ethicon's procedure for terminating/transferring employees (PR 553-003; attached as Exhibit B) provides that managers are responsible for instructing departing employees/contractors to review their paper and electronic files against any Preservation Notices in effect, prior to separation, using the PS-00000117 procedure. Departing employees are responsible for working with their Manager to complete the "Exit Checklist & Certificate of Compliance For Records Disposition" prior to exiting Ethicon in order to appropriately disposition their records pursuant to business requirements and active preservation hold notices. If required by the terminating/transferring employee's or contractor's/consultant's Manager/Supervisor, Information Technology representatives are responsible for obtaining the computer files and providing a copy of the materials to the Manager/Supervisor in a CD or other format.

VI. PRESERVATION ISSUES HAVE BEEN IDENTIFIED IN CONNECTION WITH PELVIC MESH LITIGATION

47. Notwithstanding Ethicon's efforts documented above, during the course of pelvic mesh litigation over the past year, the parties have raised issues regarding certain individuals' compliance with litigation hold notices, as well as the efficacy of certain procedures regarding departing employees with a potential impact on record retention.

48. In April 2013, I was asked to investigate concerns regarding former sales representatives and their compliance with retention procedures and litigation hold notices. My investigation later expanded to other designated former employees.

49. Specifically, Ethicon was unable to collect and produce electronic data directly from certain former employees who had been identified as custodians of documents potentially relevant to pelvic mesh litigation. In certain cases, hard copy/paper materials were collected and produced on behalf of the individual as part of the individual's "custodial file." In other

instances, the loss of the electronic data resulted in the individual's "custodial file" containing no associated documents.

50. In connection with my fact-finding, I determined that these losses of electronic data occurred despite Ethicon's good faith efforts to ensure compliance with litigation hold notices through policies, procedures, and training. In certain rare circumstances, the electronic data was lost because the former employee misunderstood the requirements to preserve documents, notwithstanding the litigation hold notices issued. In other circumstances (and this was more frequently the case), the employee understood and properly preserved documents while working at Ethicon, but upon the employee's departure or separation from the company, his or her electronic data were not properly transferred to the company. That is, the contents of the employee's hard drive were not preserved because either the manager did not complete the close-out audit or the employee did not communicate the information to be preserved (or incorrectly assumed it would be preserved).

VII. ETHICON HAS TAKEN RECENT ACTIONS TO PROMOTE COMPLIANCE WITH PRESERVATION OBLIGATIONS

51. On an ongoing basis, Ethicon examines and assesses its policies, procedures, training and technology relating to record retention, including legal hold obligations, in light of their efficacy, as well as corporate organizational structure and growth, evolving regulatory and legal requirements, technological developments, accepted best practices, and other considerations.

52. Over the past year or so, Ethicon has implemented a number of measures to secure its ability to meet legal hold obligations going forward, including certain actions that were taken in response to issues identified in connection with this MDL.

53. As to sales representatives, in December 2012, Ethicon instructed C3i, the third party vendor that manages the hardware of all sales representatives, to permanently retain all hard drive images when a sales representative separates from the company (or receives replacement equipment).

54. In addition, Ethicon took a series of steps to further educate sales representatives as to compliance with litigation hold notices. The company held a conference call encompassing approximately 150 current and former sales representatives as well as division managers during which responsibilities to comply with litigation hold notices were restated and clarified and questions were taken. I understand that another similar call is being scheduled as a further reminder.

55. Ethicon has also launched efforts to permit more centralized management and storage of documents that have traditionally resided with individual custodians. For example, in 2013, Ethicon launched Outlook Exchange 2010, which allowed emails to be saved permanently in their customary, centralized, and secure business location. Exchange 2010 removed mailbox size limits and the use of any mailbox "sweep" technology. It also removed the need (and ability) to use local PST folders to save emails that exceeded the centralized mailbox capacity.

56. Ethicon has also moved to ensure that the data of departed employees will be available for business use or collection for litigation purposes, even years after such employees have left the company. In June 2012, Ethicon began saving all hard drives of departed employees, rather than selected file/email information based on the manager's response to the departing employee's workflow ticket. In 2013, Ethicon modified its asset collection program such that, once an employee is terminated, a notice is automatically sent to the IT department to retrieve the employee's company laptop. Also in early 2013, Ethicon joined the "IT Safe"

program. Under IT Safe, once a former employee's laptop is retrieved, that individual's hard drive is shipped to the IT shared services ("ITSS") group for imaging, and all data on the hard drive is preserved.

57. In addition, Ethicon has centralized monitoring of the departure process within the human resources department (HR). Generally, HR will have oversight of the managers and supervisors working with departing employees to confirm managers' awareness and execution of the policies and procedures associated with the departure process, including with respect to departing employees' data.

VIII. RESPONSES TO SPECIFIC FACTUAL ALLEGATIONS IN PLAINTIFFS' BRIEFS

58. I have been asked to review and respond specifically to certain factual allegations set forth in Plaintiffs' Memorandum of Law and supplemental submission.

59. Plaintiffs incorrectly suggest that a 2002 audit and 2007 CAPA demonstrate that Ethicon's preservation procedures were inadequate. However, as described above, the purpose of the CAPA was to align a formal records program for Ethicon with corporate standards on an ongoing basis. Despite the shorthand description in the CAPA, my fact-finding showed that the CAPA did not take issue with Ethicon's ability to *preserve* relevant information in the case of litigation, including this litigation. Further, the CAPA had nothing to do with pelvic repair documents in particular.

60. Plaintiffs in their briefs specifically identify 22 current or former Ethicon employees about whom Plaintiffs claim retention issues.

61. As an initial matter, well over half of the individuals identified (13 of the 22) – Rick Isenberg (departed 2002), Gregory Jones (departed 2003), Amy Godwin (departed 2004), Charlotte Owens (departed 2005), Sean O'Bryan (departed 2005), Laura Angelini (departed

2005), Kendra Munchel (departed 2005), Zenobia Walji (departed 2005), Jill Schiaparelli (departed 2005), Patricia Hojnoski (departed 2006; returned in 2008 as contract employee with limited administrative responsibilities for one year), Cheryl Bogardus (departed 2007), Allison London Brown (departed 2007), and John Clay (departed 2007) – departed Ethicon before Ethicon issued its April 2008 hold notice.[1]

62. It should be expected that these 13 individuals who departed the company prior to the commencement of these cases and the issuance of a legal hold (and many years before custodial collections were conducted) would have few, if any, documents attributed to them in a "custodial file."

63. Five other individuals – Renee Selman, Ramy Mahmoud, Jennifer Paine, Price St. Hilaire, and Tom Divilio – departed the company prior to the consolidation of the New Jersey litigation in 2010.[2]

64. Plaintiffs' claims about the numbers of documents in the "custodial files" of all 22 individuals also fall flat for the independent reasons explained below.

65. In this declaration, I have alluded to the term "custodial file." It has also been used, in a different context, by Plaintiffs in their brief. The term "custodial file" is properly understood as an organizational and workflow concept in the context of document productions in

[1] Based on my review of pertinent deposition testimony and personnel files, Plaintiffs mischaracterize the Ethicon tenures and/or pelvic mesh involvement of a number of these 13 individuals. Amy Godwin worked at Ethicon only until 2004; her position in 2007 as "Director of Trial Operations" referenced by Plaintiffs was with an entirely different company – Ortho Biotech. Plaintiffs also incorrectly suggest that Kendra Munchel was Global Marketing Manager of Ethicon from 2005 to 2007; in fact, that position was with Advanced Sterilization Products. In 2005, Laura Angelini left Ethicon for Ethicon Endo-Surgery, which was not involved with pelvic mesh products; thus, when she was "re-hired in the same position" a few weeks after "quitting" in 2005, it was at Ethicon Endo-Surgery. Likewise, while Plaintiffs describe Zenobia Walji as "Worldwide Director, Strategic Planning, 2009-2012," that position was with Ethicon Endo-Surgery. Ms. Walji's involvement with Ethicon and pelvic mesh ended more than 8 years ago. Jill Schiaparelli also transferred out of Ethicon to Ethicon Endo-Surgery, and did so in 2005, not 2007, as Plaintiffs claim.

[2] Notably, Jennifer Paine left Ethicon a full year before Plaintiffs say - in December *2008*, not 2009.

litigation; that is, it can and should be understood as containing documents that have been collected directly from a particular individual.

66. Plaintiffs' use of the term "custodial file" to suggest that it represents all of the information or documents contributed by that individual to a litigation is misplaced. As explained below, the reliance on the term "custodial file" in that context is based on a misconception of the manner in which individuals create, manage, transmit, and share information and documents in a modern corporate environment, such as within Ethicon.

67. In a modern corporate environment, technology infrastructure is increasingly designed to encourage users to create and manage documents and information in centrally stored and managed locations, such as Microsoft SharePoint sites, group or department shares, databases, and other electronic systems, rather than on a drive to which only a single user has access.

68. The above is true of Ethicon. Indeed, as discussed at the beginning of this declaration, the key design, regulatory, marketing, complaints and other post-market surveillance documents regarding the pelvic mesh products at issue in this MDL are maintained centrally at Ethicon, and have been collected and produced, apart from any "custodial files."

69. Further, the use of central filing locations such as L drives by many workgroups and associated individuals indicates that even drafts or non-final work product of a particular individual may be stored in that shared location, and therefore be available for collection, although not necessarily always attributable to that individual for collection and production purposes.

70. In addition, given the collaborative working environment of Ethicon and the fact that emails necessarily have both a sender and a recipient (or recipients), many documents of a

custodial nature that are in the possession of one individual are also likely to be in the possession of other individuals, some of whom may work in the same functional or subject matter area. Plaintiffs in their brief complain that the "custodial files" of various individuals contained no or very few documents. But in fact basic searches of names and/or email addresses show that substantial numbers of email communications and attachments to or from each of the 22 individuals cited by Plaintiffs have been produced in the MDL and can be located within the production. These emails are identified on the schedule below:

Identified Individual	**Approx. number of produced emails and attachments to/from Identified Individual**
Renee Selman	8,503
Ramy Mahmoud	3,013
Charlotte Owens	3,664
Sean O'Bryan	4,951
Laura Angelini	4,190
Jennifer Paine	4,632
Price St. Hilaire	17,125
Cheryl Bogardus	5,520
Greg Jones	1,299
Rick Isenberg	1,618
Patricia Hojnoski	3,800
Jill Schiaparelli	3,586
Paul Courts	706
Troy Mohler	2,375
Allison London Brown	14,651

John Clay	984
Kendra Munchel	2,619
Tom Divilio	2,208
Amy Godwin	1,665
Susanne Landgrebe	8,415
Zenobia Walji	5,578
Nancy Leclair	4,430

71. Because of the way individuals in a modern corporate electronic environment create, manage, transmit and/or share information and documents, even assuming perfect compliance with litigation hold procedures, it is very unlikely that any "custodial file" would ever include all documents created or received by that custodian. Unlike a broker-dealer workplace, in which email "journaling" is mandated for regulatory compliance purposes, Ethicon, like other corporate email users that do not journal, could not possibly perfectly capture every email. However, like other medical device companies, Ethicon has policies and procedures to preserve emails that are classified as part of its regulatory framework, regardless of legal hold status. Indeed, as mentioned above, centralized collections of materials like the Design History File and 510(k) files contain emails, and it is not disputed that Ethicon has produced to Plaintiffs those centralized collections, including emails.

72. There are many sources of an employee's documents, only one of which is his or her "custodial file." This is particularly true for custodians who have departed the company prior to collection. Indeed, the concept of a "custodial file" as applied to a former employee is a

misnomer, as the documents of the former employee typically are transferred or moved to the custody of someone other than the former employee who has departed.

73. Thus, even where an individual's "custodial file" does not contain any documents, as shown above, it is possible (and in fact is the case here) that substantial numbers of that individual's documents (including email communications) have been collected and produced, from file shares, databases, and other enterprise electronic systems, as well as from other individuals' "custodial files."

74. In addition to the above, other findings from my investigation also fail to support the notion that documents "missing" from particular individuals' "custodial files" were necessarily relevant. To the contrary, as explained below, Ethicon's collection methodology was designed to maximize the production of relevant materials from multiple sources.

75. As an initial matter, Ethicon's collection process has several layers of built-in redundancies. Ethicon's collection included both central sources and custodians, and as to custodians, multiple individuals within functional areas were targeted for custodial collection.

76. For example, while it is true that fewer than 2,000 documents were produced as part of the "custodial file" of one of the more than 35 individuals working in the area of marketing on whom custodial collections were performed (Laura Angelini), more than 330,000 documents were produced in the "custodial files" of other individuals employed in a marketing capacity, not to mention the marketing documents produced from central, group, or shared sources. Plaintiffs' presumption that key marketing documents were lost simply does not follow from the observation that Laura Angelini's "custodial file" contained fewer documents than they might have expected.

Likewise, the "custodial file" of Charlotte Owens, who worked in Medical Affairs, contained no documents. But more 280,000 documents numbering more than from 20 other custodians employed in a medical or clinical capacity have been produced.

77. These redundancies should also be considered in evaluating Plaintiffs' complaints about John Clay. John Clay was merely one of more than 15 different individuals working in Regulatory Affairs who was identified for custodial collection and, unlike several other of those individuals, he has not been deposed in either a corporate representative or individual capacity. Voluminous regulatory materials have been produced in connection with other "custodial files," not to mention central source materials.

78. Indeed, the redundant processes that Ethicon has built into its document collection is further demonstrated by looking at the collection and production history of two emails:

a. Exhibit C to this declaration is an email from a Professional Education Manager to several recipients, including Price St. Hilaire, announcing a cadaver lab training course for surgeons. Although this email was not collected directly from Price St. Hilaire, *it was collected from eight other custodians* and produced to Plaintiffs.

b. Likewise, Exhibit D is an email from Brian Luscombe, the United States Product Director for Pelvic Reconstructive Surgery, to several recipients, including Paul Courts and Troy Mohler, providing meeting minutes to the Incontinence & Pelvic Organ Prolapse Brand Team. Although this email was not collected directly from Paul Courts or Troy Mohler, *it was collected from 15 other custodians* and produced to Plaintiffs.

79. These two emails were not "lost" simply because they were not associated with the "custodial files" of Mr. St. Hilaire, Mr. Courts, or Mr. Mohler. To the contrary, each of these emails was collected from numerous other custodians and were produced to Plaintiffs. Plaintiffs can see the content of each of these emails. Plaintiffs can also see that the first email was sent to Mr. St. Hilaire, among others, and that the second email was sent to Mr. Courts and Mr. Mohler, as well as other individuals. In short, Plaintiffs already have the same information regarding these emails that they would have had in the event that Ethicon has associated the emails with the "custodial files" of Mr. St. Hilaire, Mr. Courts, and Mr. Mohler.

80. Plaintiffs in their brief indicate that the production of small numbers of documents in the custodial files of certain individuals means that relevant documents must have been lost. Based on my investigation, this suggestion is unfounded as applied to a number of the individuals Plaintiffs identified.

81. First, Plaintiffs' suggestion is particularly unfounded with respect to current and former sales representatives. I spoke with a number of different sales representatives in the course of my investigation and each emphasized that the role of a medical device sales representative at Ethicon is not document-intensive.

82. Accordingly, it is unsurprising to me that, as compared to non-sales representative employees, relatively few documents were directly collected from sales representatives such as Paul Courts and Troy Mohler (who have been identified by Plaintiffs), and relatively few documents determined to be relevant were produced as part of their respective custodial files. Nevertheless, it should be noted that the "custodial files" of Mr. Courts and Mr. Mohler each contained hundreds of documents.

83. Further, as to Troy Mohler in particular, he testified unequivocally that he read, understood, and complied with Ethicon's record retention policies and legal hold notices and did not destroy any documents that should have been preserved. To the contrary, he testified that he provided his documents to Ethicon upon his departure. These documents included marketing, training, and professional education materials which would have been produced from central sources, such as Blue.

84. In addition, my fact-finding regarding other individuals specifically identified by Plaintiffs (including interviews with such individuals and/or review of sworn testimony) undercuts the presumption that these individuals would have had significant volumes of documents relevant to pelvic mesh litigation that cannot be located from other sources, for example:

a. Renee Selman – Ms. Selman testified that, due to her position, she was not the author of many documents and that such documents likely would be associated with other individuals' "custodial files."

b. Tom Divilio – Mr. Divilio had little to no involvement with pelvic mesh products. At most, he may have had minimal involvement in 1998-1999 before any hold notices related to pelvic mesh products were issued.

c. Greg Jones – As worldwide director of Regulatory Affairs and Quality Assurance for Gynecare, Mr. Jones supervised project managers who were primarily responsible for document-intensive tasks, such as the creation of regulatory submissions. Moreover, while Plaintiffs state that Mr. Jones "kept electronic copies" of 510(k)s and FDA correspondence – incorrectly implying that such documents were somehow unavailable to Plaintiffs by

virtue of them not being associated with Mr. Jones's "custodial file" – relevant 510(k)s that would include such materials have been produced from the appropriate central sources of record.

d. Susanne Landgrebe – Ms. Landgrebe was involved in the research and development of pelvic mesh products up to approximately 2005. In 2009, Ms. Landgrebe's hard drive crashed, and she was issued a new computer. Since she would have lost any relevant electronic documents at the time of the crash, it is unsurprising that her "custodial file" has a small volume of materials.

85. Finally, in my fact-finding, I did not identify a single instance in which an Ethicon employee selectively and intentionally destroyed documents known to be relevant to the pelvic mesh litigation.

86. Rather, any losses of data were attributable to some type of misunderstanding by an employee and/or a miscommunication between a departing employee and his or her manager.

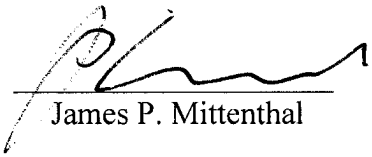
87. This is true of the disposition of Ms. Selman's hard drive. As Plaintiffs themselves acknowledge, Ms. Selman was aware of the litigation hold and complied with it during her time at Ethicon. The loss of her data occurred when she and those who were responsible for her materials upon her departure failed to identify to IT the need to retain her data in connection with applicable legal holds. Rather, they incorrectly assumed that the data would be held even in the absence of their identifying that need.

88. These misunderstandings and miscommunications led to losses of data that were not at the custodian's discretion – there was no deletion of specific emails, email folders, or documents regarding any particular subject matter.

89. Moreover, as demonstrated above, it is reasonable to expect that the vast majority of any relevant documents not found in a particular individual's custodial file were collected and produced from central sources and/or other individuals' "custodial files."

I represent that the foregoing statements are true under the penalties of perjury.

Dated: January 10, 2014



James P. Mittenthal

Exhibit A


Menu
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1 Introduction
2 Records and Convenience Information
3 Roles and Responsibilities
4 Managing Electronic Records
5 Document Preservation Notice
6 Records Retention
7 Vital Records, Records Clean-Up, and Compliance Audits
8 Quiz
Key
Unavailable
Available
Current
Complete


Records and Information Management Training - Windows Internet Explorer
WWRIM
Worldwide Records & Information Management
Records and Information Management Training
Introduction
Welcome
Welcome to the Records and Information Management training. This is an online course that will provide the associate with an understanding of the main requirements of the Records and Information Management (RIM) program within Johnson & Johnson.
Objectives
Our Records and Information Management (RIM) program is designed to ensure that records are:
Created, managed, and retained as required for business purposes
Retained and kept secure in an appropriate manner
Not kept beyond their retention period, unless required by law
Protected from destruction if required for litigation, audit, or other investigation
Available and readily retrievable during their lifecycle
Upon completion of this course, you will be able to:
Describe the requirements of the Worldwide Records and Information Management program
Understand your responsibilities in complying with those requirements
Resources
Navigation
Johnson & Johnson
Click each item. Then click Next.
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Records and Information Management Training - Windows Internet Explorer
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Records and Information Management Training
Introduction
Course Objectives
Upon completion of this course, you will be able to:
Understand the Worldwide Records and Information Management program requirements
Describe the main components of a Records and Information Management program
Define what a record is and explain the guidelines for creating a record
Describe the roles and responsibilities involved with Records and Information Management
Identify what determines whether information is a "record" or whether it is "Convenience Information"
Follow the guidelines for managing electronic records such as Microsoft Word or Excel documents, e-mails, and documents stored on portable external media such as "jump drives" or CDs
Follow the proper steps to comply with a Document Preservation Notice
Interpret and apply the Records Retention Schedule
Learn the definition and rules for a Records Clean-Up Event
Understand how to identify and protect a Vital Record
Understand your role in participating in Records Compliance Audits
Welcome to Records and Information Management Training
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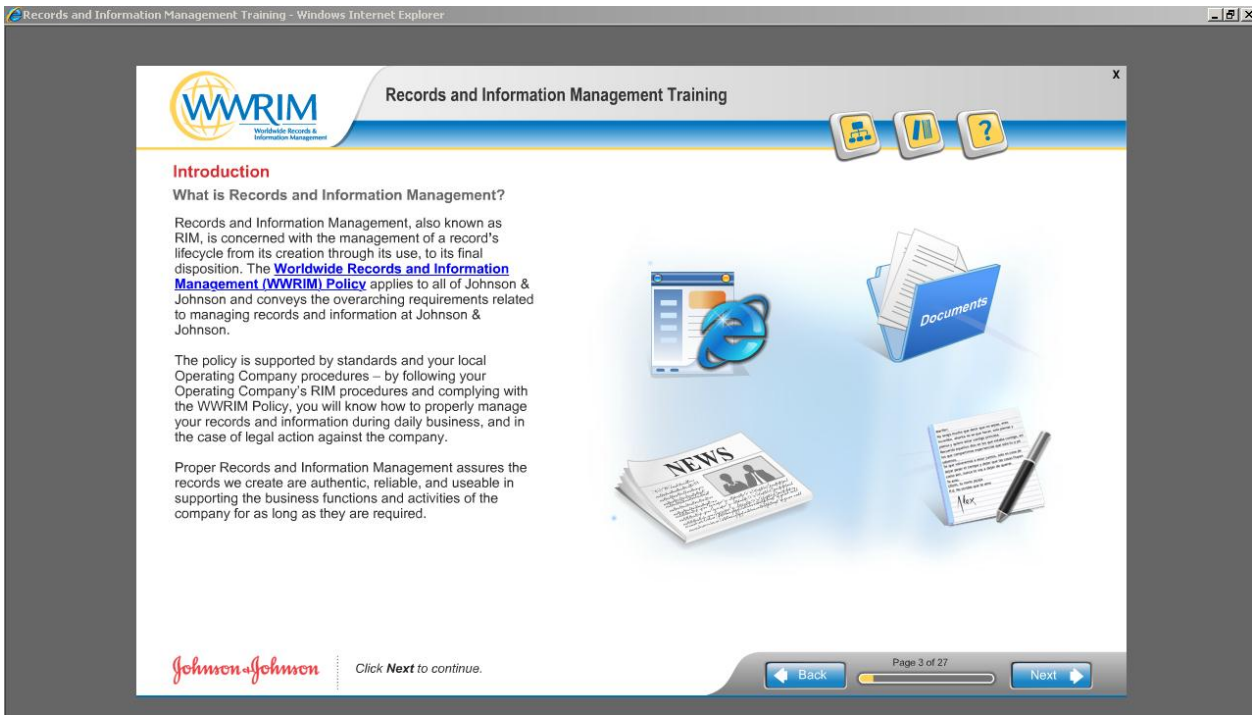
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Introduction
What is Records and Information Management?
Records and Information Management, also known as RIM, is concerned with the management of a record's lifecycle from its creation through its use, to its final disposition. The Worldwide Records and Information Management (WWRIM) Policy applies to all of Johnson & Johnson and conveys the overarching requirements related to managing records and information at Johnson & Johnson.
The policy is supported by standards and your local Operating Company procedures – by following your Operating Company's RIM procedures and complying with the WWRIM Policy, you will know how to properly manage your records and information during daily business, and in the case of legal action against the company.
Proper Records and Information Management assures the records we create are authentic, reliable, and useable in supporting the business functions and activities of the company for as long as they are required.
Documents
NEWS
Johnson & Johnson
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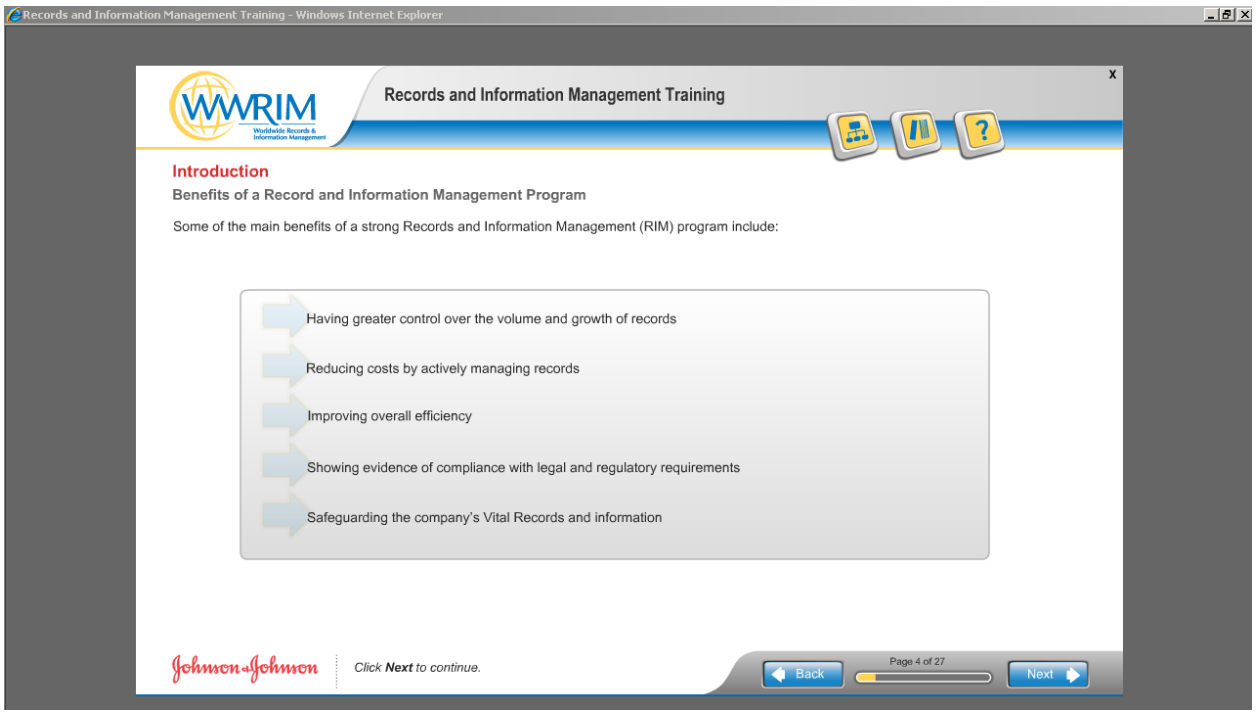
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Records and Information Management Training
Introduction
Benefits of a Record and Information Management Program
Some of the main benefits of a strong Records and Information Management (RIM) program include:
Having greater control over the volume and growth of records
Reducing costs by actively managing records
Improving overall efficiency
Showing evidence of compliance with legal and regulatory requirements
Safeguarding the company's Vital Records and information
Johnson & Johnson
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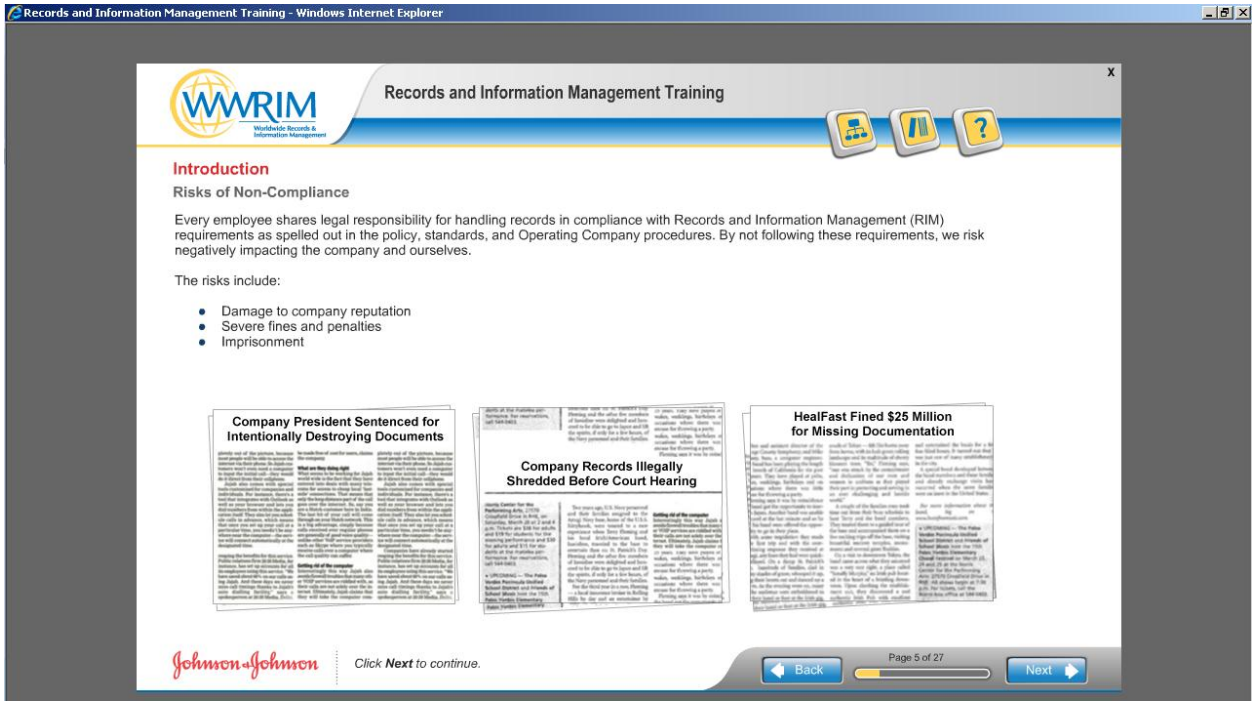
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Introduction
Risks of Non-Compliance
Every employee shares legal responsibility for handling records in compliance with Records and Information Management (RIM) requirements as spelled out in the policy, standards, and Operating Company procedures. By not following these requirements, we risk negatively impacting the company and ourselves.
The risks include:
Damage to company reputation
Severe fines and penalties
Imprisonment
Company President Sentenced for Intentionally Destroying Documents
Company Records Illegally Shredded Before Court Hearing
HealFast Fined $25 Million for Missing Documentation
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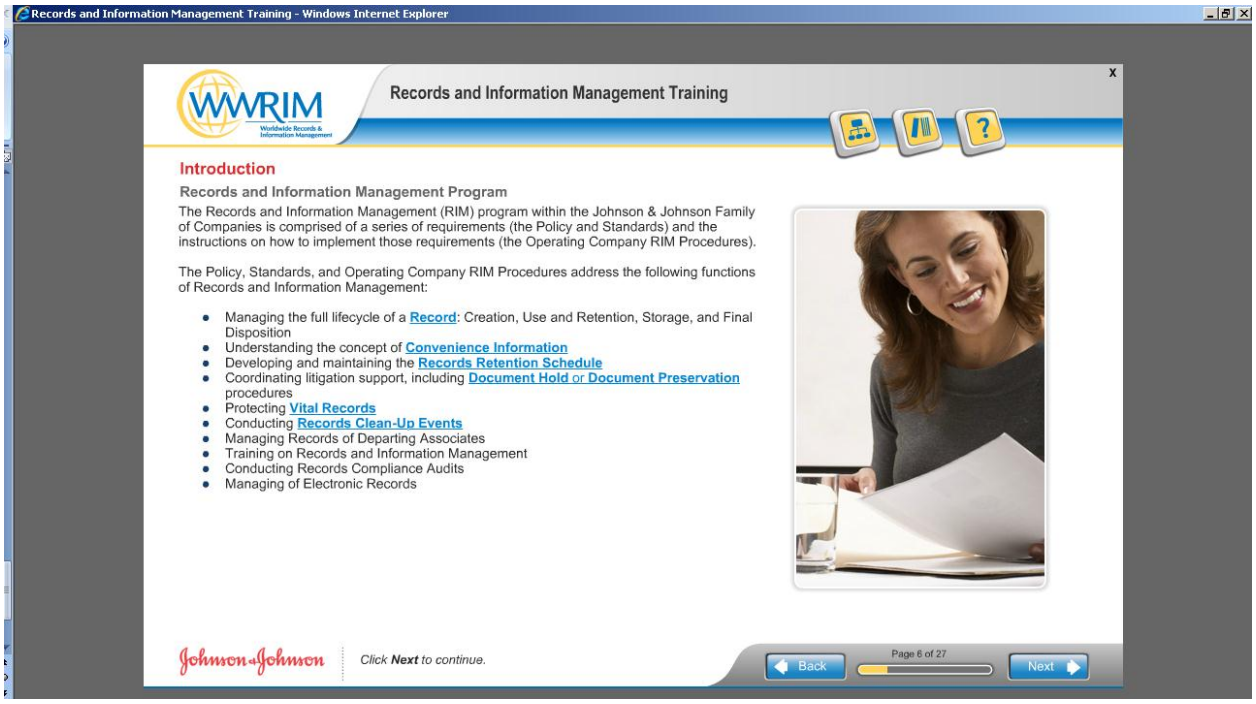
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Introduction
Records and Information Management Program
The Records and Information Management (RIM) program within the Johnson & Johnson Family of Companies is comprised of a series of requirements (the Policy and Standards) and the instructions on how to implement those requirements (the Operating Company RIM Procedures).
The Policy, Standards, and Operating Company RIM Procedures address the following functions of Records and Information Management:
Managing the full lifecycle of a Record: Creation, Use and Retention, Storage, and Final Disposition
Understanding the concept of Convenience Information
Developing and maintaining the Records Retention Schedule
Coordinating litigation support, including Document Hold or Document Preservation procedures
Protecting Vital Records
Conducting Records Clean-Up Events
Managing Records of Departing Associates
Training on Records and Information Management
Conducting Records Compliance Audits
Managing of Electronic Records
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Introduction
Lifecycle of Records and Information
Records and information have a lifecycle – that is, they are created, they are used, they are retained as appropriate, they can be stored while waiting for their retention times to be met, and they are disposed of at the end of their lifecycle.
Records and Information Management (RIM) provides a framework for managing records and information throughout all phases of the lifecycle.
For example, the Records Retention Schedule, which is essentially a listing of record types and the amount of time those records must be kept in order to comply with business and legal requirements, is a tool used to help manage the retention and storage phases of the record's lifecycle.
To help with storage of records which have not yet met their retention times but which aren't used on a daily basis, the Operating Company RIM department offers an inactive records storage service.
Finally, records and information do eventually reach a state of final disposition. Often this final disposition involves a controlled destruction of the record after it has met all of its lifecycle (and legal) requirements. However, sometimes a record's final disposition at any given point of review will be an indefinite retention due to ongoing legal or regulatory requirements.
We'll learn more about some of these topics later in the course, but right now we'll begin with a description of what is considered a "record".
Create
Use
Lifecycle of Records and Information
Store
Dispose
Johnson & Johnson
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Records and Information Management Training

Records and Convenience Information

Records

We create records every day.

Records are recorded information, regardless of medium or characteristics, created or received by an organization in meeting legal obligations or in transacting business. That is, records can exist in a paper form, such as a paper calendar book, in electronic form, such as an email message or file on a CD, in film form, such as a video tape, and many other forms.

Company records are considered valuable assets. As an associate, you are accountable for the records you create and receive. If you do not comply with Records and Information Management requirements, you may be subject to disciplinary action including, but not limited to, employment termination and criminal or civil liability.

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Records and Convenience Information

Check Your Understanding

Here are some common pieces of information you may come across during the normal course of business.

Which of the following are considered records? Check the ones that apply.

- A. Online calendar
- B. Electronic invoice for vendor services
- C. "Sticky" notes, or other handwritten notes, attached to a formal document
- D. Audio recording of a meeting
- E. Word document containing meeting minutes
- F. Graphic of the company logo
- G. Videotape of meeting
- H. E-mail discussing project spending

Incorrect. All of the items listed are considered to be "records".

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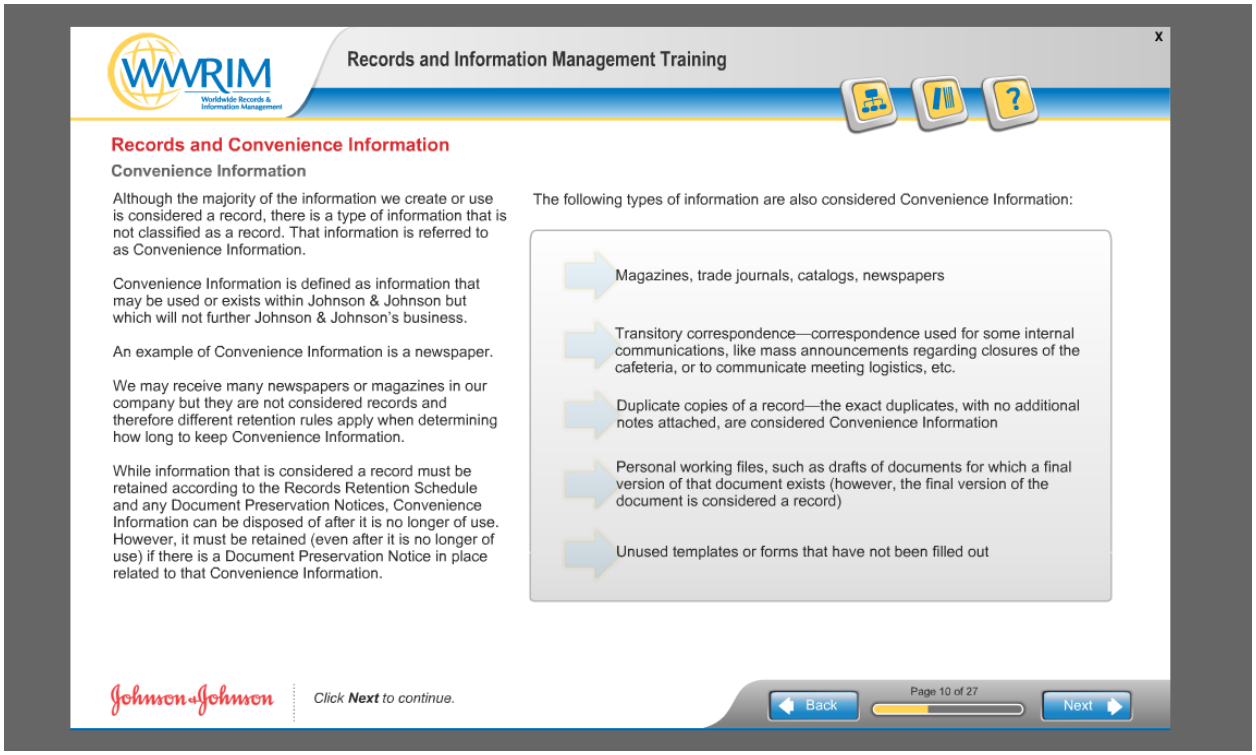
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Records and Convenience Information
Convenience Information
Although the majority of the information we create or use is considered a record, there is a type of information that is not classified as a record. That information is referred to as Convenience Information.
Convenience Information is defined as information that may be used or exists within Johnson & Johnson but which will not further Johnson & Johnson's business.
An example of Convenience Information is a newspaper.
We may receive many newspapers or magazines in our company but they are not considered records and therefore different retention rules apply when determining how long to keep Convenience Information.
While information that is considered a record must be retained according to the Records Retention Schedule and any Document Preservation Notices, Convenience Information can be disposed of after it is no longer of use. However, it must be retained (even after it is no longer of use) if there is a Document Preservation Notice in place related to that Convenience Information.
The following types of information are also considered Convenience Information:
Magazines, trade journals, catalogs, newspapers
Transitory correspondence—correspondence used for some internal communications, like mass announcements regarding closures of the cafeteria, or to communicate meeting logistics, etc.
Duplicate copies of a record—the exact duplicates, with no additional notes attached, are considered Convenience Information
Personal working files, such as drafts of documents for which a final version of that document exists (however, the final version of the document is considered a record)
Unused templates or forms that have not been filled out
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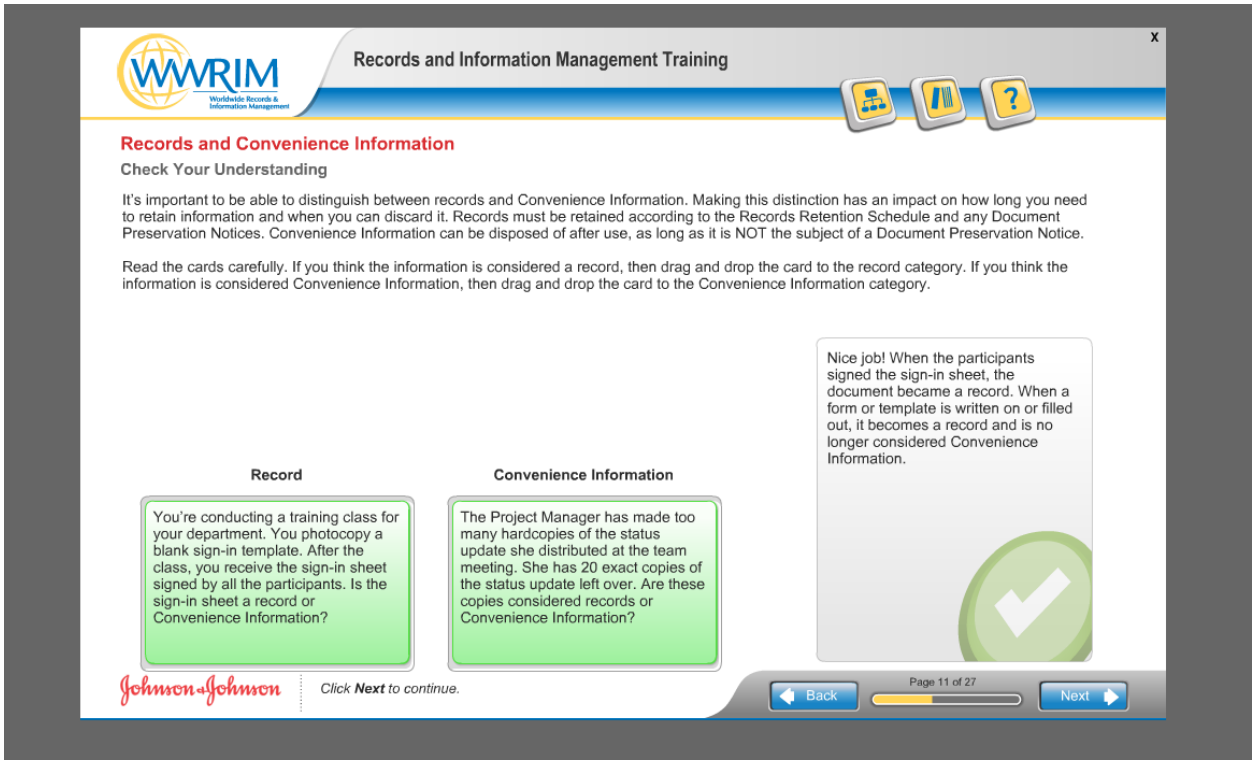
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Records and Convenience Information
Check Your Understanding
It's important to be able to distinguish between records and Convenience Information. Making this distinction has an impact on how long you need to retain information and when you can discard it. Records must be retained according to the Records Retention Schedule and any Document Preservation Notices. Convenience Information can be disposed of after use, as long as it is NOT the subject of a Document Preservation Notice.
Read the cards carefully. If you think the information is considered a record, then drag and drop the card to the record category. If you think the information is considered Convenience Information, then drag and drop the card to the Convenience Information category.
Record
Convenience Information
You're conducting a training class for your department. You photocopy a blank sign-in template. After the class, you receive the sign-in sheet signed by all the participants. Is the sign-in sheet a record or Convenience Information?
The Project Manager has made too many hardcopies of the status update she distributed at the team meeting. She has 20 exact copies of the status update left over. Are these copies considered records or Convenience Information?
Nice job! When the participants signed the sign-in sheet, the document became a record. When a form or template is written on or filled out, it becomes a record and is no longer considered Convenience Information.
Johnson & Johnson
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Records and Information Management Training

Roles and Responsibilities

Everyone has a Role

Each of us has a responsibility to manage company records according to Records and Information Management policy and standards. Some of us have specialized roles in addition to our employee responsibilities.

Do you know what your role is? Let's see what these employees have to say about their role in Records and Information Management.

Records Manager

Records Coordinator

J&J Law Department

Supervisor

Hi, I'm the supervisor for a department that has both employees and contractors. I'm responsible for ensuring my direct reports have the opportunity to learn and practice good records management.

I also ensure that any associates leaving my department have managed and handed off their records according to procedures before they leave the department. If the associate doesn't address his or her records prior to departure, as the supervisor I am responsible for taking on this task. Also, as a sponsor for several contractors, I'm responsible for ensuring that a departing contractor hands off all of their company records to me prior to their departure.

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Records and Information Management Training

Roles and Responsibilities

Your Role

You've learned the specific roles involved in Records and Information Management (RIM), but remember that YOU also play a very important role.

You create records or receive records during everyday business, and it's your responsibility to:

- Comply with all Records and Information Management (RIM) policy, standards, and procedures
- Review your records at least once a year
- Retain records required for litigation, audit, tax, or regulatory investigation
- Discard records no longer needed for the business in accordance with RIM procedures and local company Records Retention Schedule

When you leave your company, you must transition all paper and electronic records for which you are responsible to your manager or supervisor as instructed by your company's procedures.

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Records and Information Management Training

Managing Electronic Records

Content is Key

Records Management requirements apply to the content of a record, not to the media on which it resides. This means that regardless of whether a record is paper, electronic, or film-based, it is the content of the record that determines how that record is retained.

For example, an official meeting agenda that is stored electronically as a Word document on your network share drive is retained the same amount of time (and is subject to the same legal requirements) as if the official meeting agenda were printed on paper.

Further, e-mails also have retention times based on their content. So it is a good practice to limit the number of topics you "discuss" on a single e-mail as that will make it easier to determine the content of that e-mail and classify it according to the Records Retention Schedule.

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*Click **Next** to continue.*

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Records and Information Management Training

Managing Electronic Records

Content is Key

Records Management requirements apply to the content of a record, not to the media on which it resides. This means that regardless of whether a record is paper, electronic, or film-based, it is the content of the record that determines how that record is retained.

For example, an official meeting agenda that is stored electronically as a Word document on your network share drive is retained the same amount of time (and is subject to the same legal requirements) as if the official meeting agenda were printed on paper.

Further, e-mails also have retention times based on their content. So it is a good practice to limit the number of topics you "discuss" on a single e-mail as that will make it easier to determine the content of that e-mail and classify it according to the Records Retention Schedule.

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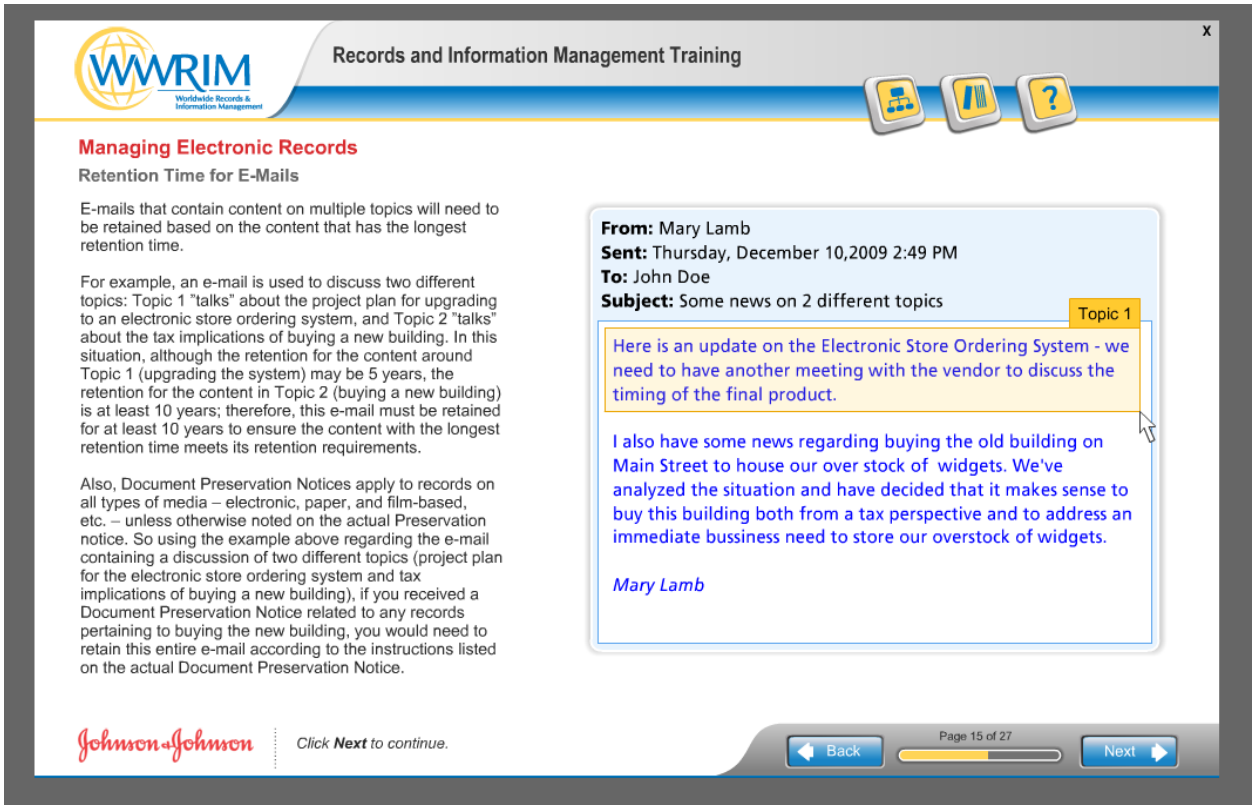
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Managing Electronic Records
Retention Time for E-Mails
E-mails that contain content on multiple topics will need to be retained based on the content that has the longest retention time.
For example, an e-mail is used to discuss two different topics: Topic 1 "talks" about the project plan for upgrading to an electronic store ordering system, and Topic 2 "talks" about the tax implications of buying a new building. In this situation, although the retention for the content around Topic 1 (upgrading the system) may be 5 years, the retention for the content in Topic 2 (buying a new building) is at least 10 years; therefore, this e-mail must be retained for at least 10 years to ensure the content with the longest retention time meets its retention requirements.
Also, Document Preservation Notices apply to records on all types of media – electronic, paper, and film-based, etc. – unless otherwise noted on the actual Preservation notice. So using the example above regarding the e-mail containing a discussion of two different topics (project plan for the electronic store ordering system and tax implications of buying a new building), if you received a Document Preservation Notice related to any records pertaining to buying the new building, you would need to retain this entire e-mail according to the instructions listed on the actual Document Preservation Notice.
From: Mary Lamb
Sent: Thursday, December 10,2009 2:49 PM
To: John Doe
Subject: Some news on 2 different topics
Topic 1
Here is an update on the Electronic Store Ordering System - we need to have another meeting with the vendor to discuss the timing of the final product.
I also have some news regarding buying the old building on Main Street to house our over stock of widgets. We've analyzed the situation and have decided that it makes sense to buy this building both from a tax perspective and to address an immediate bussiness need to store our overstock of widgets.
Mary Lamb
Johnson & Johnson
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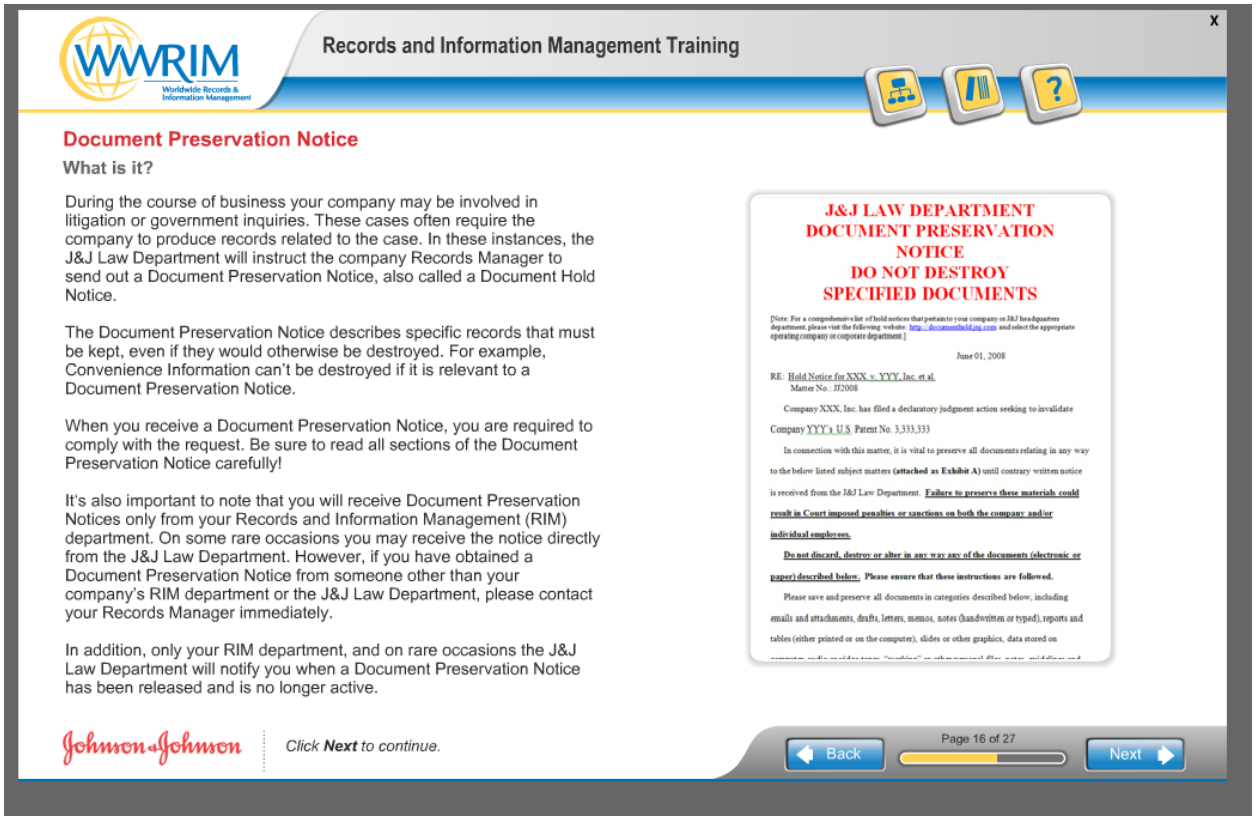
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Document Preservation Notice
What is it?
During the course of business your company may be involved in litigation or government inquiries. These cases often require the company to produce records related to the case. In these instances, the J&J Law Department will instruct the company Records Manager to send out a Document Preservation Notice, also called a Document Hold Notice.
The Document Preservation Notice describes specific records that must be kept, even if they would otherwise be destroyed. For example, Convenience Information can't be destroyed if it is relevant to a Document Preservation Notice.
When you receive a Document Preservation Notice, you are required to comply with the request. Be sure to read all sections of the Document Preservation Notice carefully!
It's also important to note that you will receive Document Preservation Notices only from your Records and Information Management (RIM) department. On some rare occasions you may receive the notice directly from the J&J Law Department. However, if you have obtained a Document Preservation Notice from someone other than your company's RIM department or the J&J Law Department, please contact your Records Manager immediately.
In addition, only your RIM department, and on rare occasions the J&J Law Department will notify you when a Document Preservation Notice has been released and is no longer active.
J&J LAW DEPARTMENT
DOCUMENT PRESERVATION NOTICE
DO NOT DESTROY
SPECIFIED DOCUMENTS
June 01, 2008
Company XXX, Inc. has filed a declaratory judgment action seeking to invalidate Company YYY's U.S. Patent No. 3,333,333
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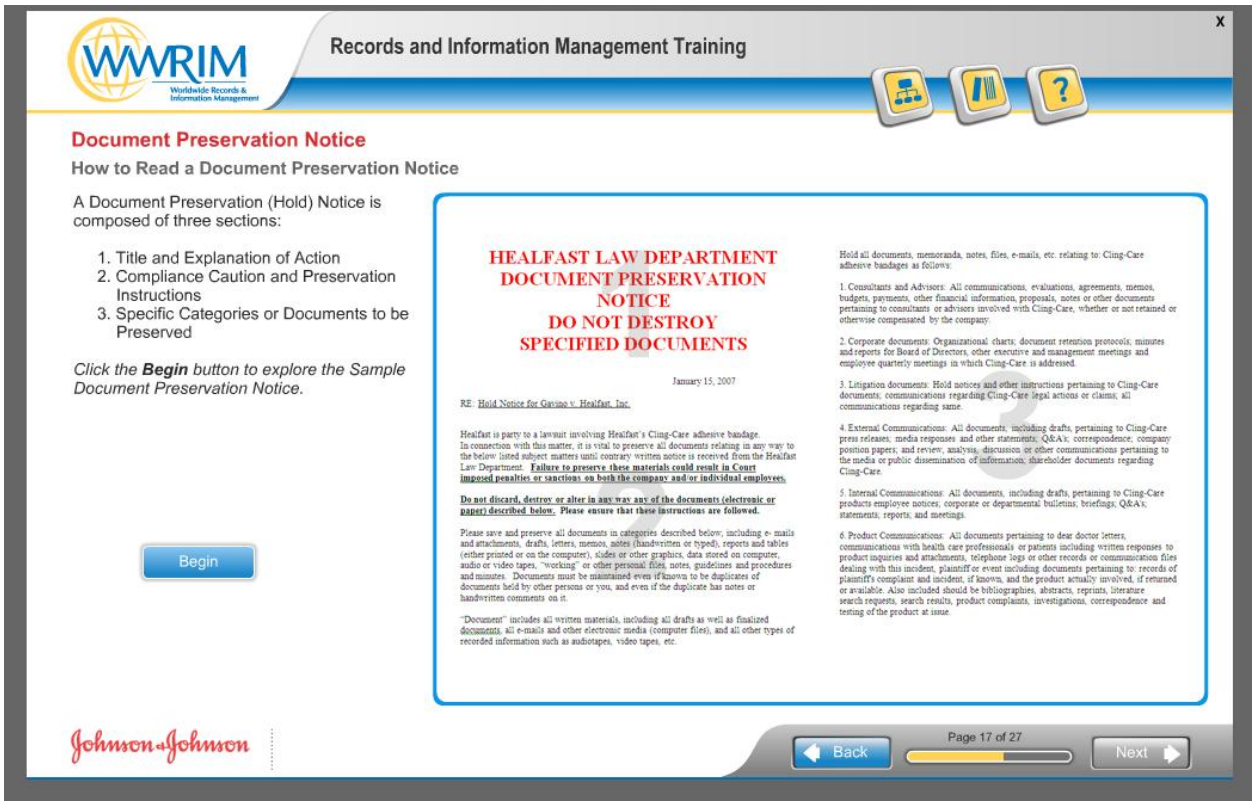
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Document Preservation Notice
How to Read a Document Preservation Notice
A Document Preservation (Hold) Notice is composed of three sections:
1. Title and Explanation of Action
2. Compliance Caution and Preservation Instructions
3. Specific Categories or Documents to be Preserved
Click the Begin button to explore the Sample Document Preservation Notice.
Begin
HEALFAST LAW DEPARTMENT
DOCUMENT PRESERVATION NOTICE
DO NOT DESTROY
SPECIFIED DOCUMENTS
January 15, 2007
RE: Hold Notice for Gavino v. Healfast, Inc.
Healfast is party to a lawsuit involving Healfast's Cling-Care adhesive bandage. In connection with this matter, it is vital to preserve all documents relating in any way to the below listed subject matters until contrary written notice is received from the Healfast Law Department. Failure to preserve these materials could result in Court imposed penalties or sanctions on both the company and/or individual employees.
Do not discard, destroy or alter in any way any of the documents (electronic or paper) described below. Please ensure that these instructions are followed.
Please save and preserve all documents in categories described below, including e- mails and attachments, drafts, letters, memos, notes (handwritten or typed), reports and tables (either printed or on the computer), sides or other graphics, data stored on computer, audio or video tapes, "working" or other personal files, notes, guidelines and procedures and minutes. Documents must be maintained even if known to be duplicates of documents held by other persons or you, and even if the duplicate has notes or handwritten comments on it.
"Document" includes all written materials, including all drafts as well as finalized documents, all e-mails and other electronic media (computer files), and all other types of recorded information such as audiotapes, video tapes, etc.
Hold all documents, memoranda, notes, files, e-mails, etc. relating to: Cling-Care adhesive bandages as follows:
1. Consultants and Advisors: All communications, evaluations, agreements, memos, budgets, payments, other financial information, proposals, notes or other documents pertaining to consultants or advisors involved with Cling-Care, whether or not retained or otherwise compensated by the company.
2. Corporate documents: Organizational charts; document retention protocols; minutes and reports for Board of Directors, other executive and management meetings and employee quarterly meetings in which Cling-Care is addressed.
3. Litigation documents: Hold notices and other instructions pertaining to Cling-Care documents; communications regarding Cling-Care legal actions or claims; all communications regarding same.
4. External Communications: All documents, including drafts, pertaining to Cling-Care press releases, media responses and other statements; Q&A's; correspondence; company position papers; and review, analysis, discussion or other communications pertaining to the media or public dissemination of information; shareholder documents regarding Cling-Care.
5. Internal Communications: All documents, including drafts, pertaining to Cling-Care products employee notices; corporate or departmental bulletins; briefings; Q&A's; statements; reports; and meetings.
6. Product Communications: All documents pertaining to dear doctor letters, communications with health care professionals or patients including written responses to product inquiries and attachments, telephone logs or other records or communication files dealing with this incident, plaintiff or event including documents pertaining to: records of plaintiff's complaint and incident, if known, and the product actually involved, if returned or available. Also included should be bibliographies, abstracts, reprints, literature search requests, search results, product complaints, investigations, correspondence and testing of the product at issue.
Johnson & Johnson
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WWRIM
Worldwide Records & Information Management
Records and Information Management Training
Document Preservation Notice
Check Your Understanding
Nice job! Even though this document shows other products' sales figures, it does mention HealFast Cling-Care adhesive bandages.
Retain
Sales Report
(Excel Doc)
Destroy
Lunch Invite
(E-mail)
Instructions
Document Preservation Notice
Johnson & Johnson
Click Next to continue.
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WWRIM Worldwide Records & Information Management

Records and Information Management Training

Document Preservation Notice

Summary

Remember, the records referred to in a Document Preservation Notice must be held and not destroyed. If a record is not related to a Document Preservation Notice, you will follow its normal Records Retention requirements, which you will learn about in the next section of this course. Your RIM department will notify you if a Document Preservation Notice is no longer active.

Remember, only your Operating Company's RIM department or on rare occasions, the J&J Law Department, will notify you if a Document Preservation Notice is in effect or no longer in effect. If you receive notification about Document Preservation Notices from any other source, notify your Record Manager immediately so they can verify it and provide accurate direction.

Loading, please wait...

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Click **Next** to continue.

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WWRIM Worldwide Records & Information Management

Records and Information Management Training

Records Retention

Keep or Discard?

The life cycle of a record is identified by its retention period.

The retention period is the period of time that a record must be maintained by an organization because it is needed for operational, legal, fiscal, historical, or other purposes.

At the end of the retention period, a record can be discarded unless there is a Document Preservation Notice in place related to the record. Courts may view improper destruction of records as a deliberate attempt to obstruct justice or conceal harmful information.

Your company documents the retention period of records using a Records Retention Schedule. In this section, you will learn how to interpret a Records Retention Schedule and use it to correctly maintain your records.

Records retention times often vary by country and jurisdiction due to differing legal requirements. It is important when using your company's Records Retention Schedule to ensure you are referring to the retention times associated with your country.

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Click **Next** to continue.

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WWRIM
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Records and Information Management Training
Records Retention
Records Retention Schedule
Let's see the description of each heading before looking at the Records Retention Schedule.
Category
Record Title
Record Description
Trigger Event
Required Retention Period
Total Retention
This column indicates the functional category the records reside in.
The Record Title indicates the name of the record. It may define one type of document or a collection of different documents that are related but share a common retention period.
The Record Description further defines the Record Title. It may also list similar records with the same retention period that are covered by the Record Title.
The Trigger Event is an event or situation which, once it has occurred, "triggers" the start of the Required Retention Period.
The Required Retention Period is the amount of time the record needs to be retained after the trigger event occurs or is met. This period is usually displayed in years.
Total Retention indicates the total length of time the company retains the record. It encompasses the time the record is retained up to the trigger event plus the required Retention Period after the trigger event has occurred.
For example
Administration
For example
Calendars
For example
Books and/or calendars (paper and electronic) recording daily activities and appointments
For example
CY
For example
2
For example
CY+2
Click to view an example of the Records Retention Schedule
Johnson & Johnson
Click each column header. Then click Next.
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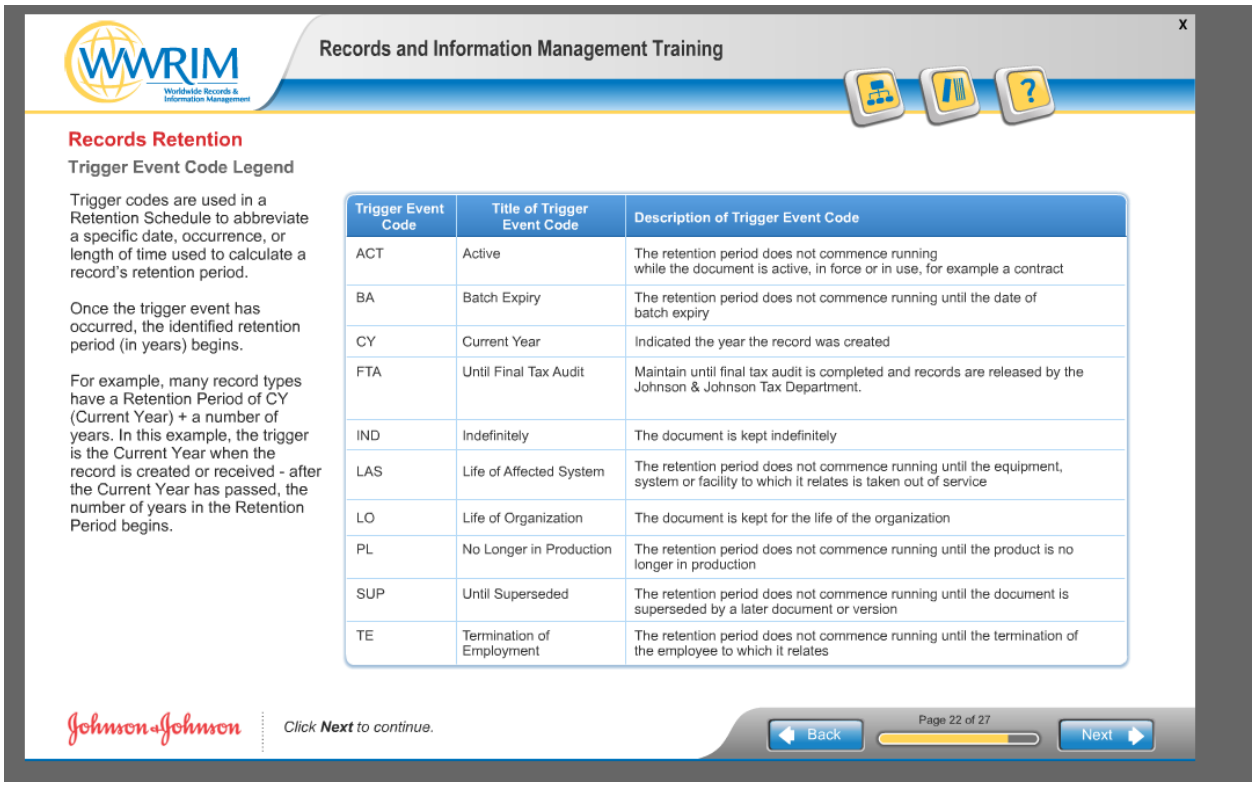
Next


WWRIM
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Records and Information Management Training
Records Retention
Trigger Event Code Legend
Trigger codes are used in a Retention Schedule to abbreviate a specific date, occurrence, or length of time used to calculate a record's retention period.
Once the trigger event has occurred, the identified retention period (in years) begins.
For example, many record types have a Retention Period of CY (Current Year) + a number of years. In this example, the trigger is the Current Year when the record is created or received - after the Current Year has passed, the number of years in the Retention Period begins.
Trigger Event Code
Title of Trigger Event Code
Description of Trigger Event Code
ACT
Active
The retention period does not commence running while the document is active, in force or in use, for example a contract
BA
Batch Expiry
The retention period does not commence running until the date of batch expiry
CY
Current Year
Indicated the year the record was created
FTA
Until Final Tax Audit
Maintain until final tax audit is completed and records are released by the Johnson & Johnson Tax Department.
IND
Indefinitely
The document is kept indefinitely
LAS
Life of Affected System
The retention period does not commence running until the equipment, system or facility to which it relates is taken out of service
LO
Life of Organization
The document is kept for the life of the organization
PL
No Longer in Production
The retention period does not commence running until the product is no longer in production
SUP
Until Superseded
The retention period does not commence running until the document is superseded by a later document or version
TE
Termination of Employment
The retention period does not commence running until the termination of the employee to which it relates
Johnson & Johnson
Click Next to continue.
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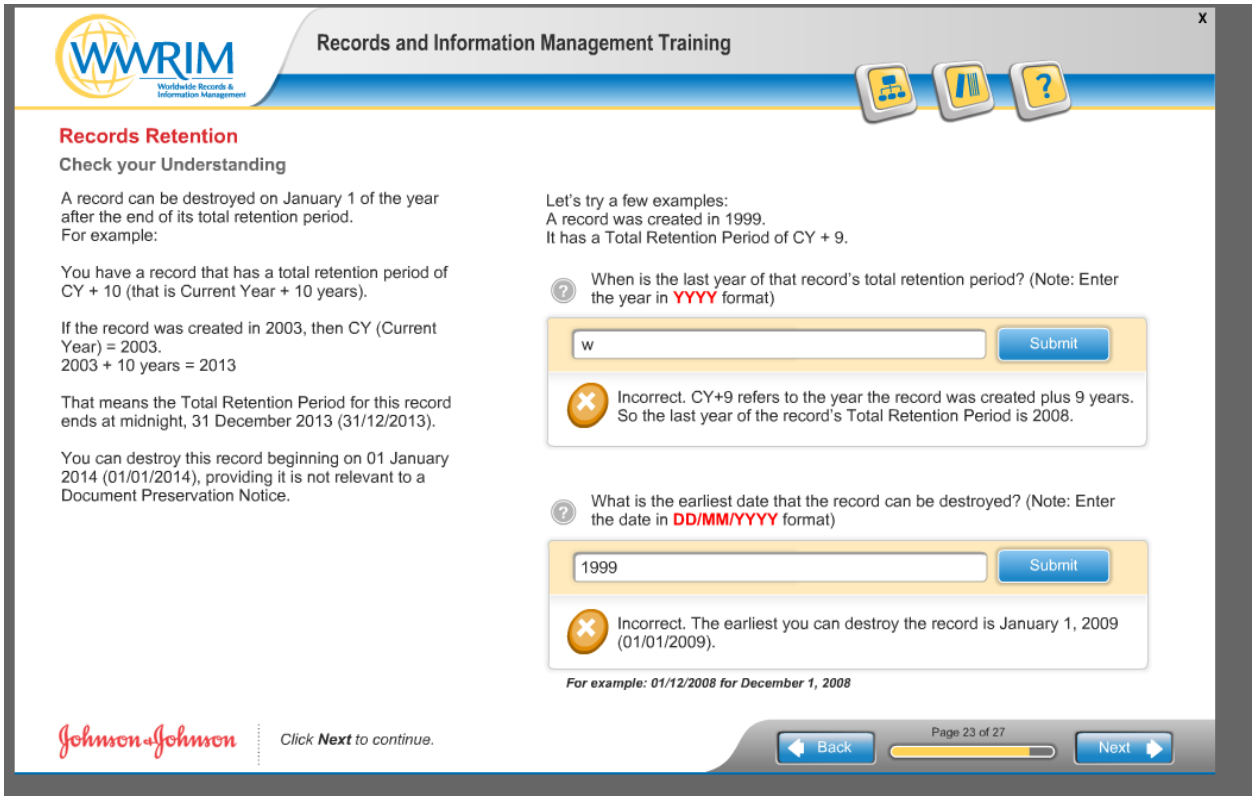
WWRIM
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Records and Information Management Training
Records Retention
Check your Understanding
A record can be destroyed on January 1 of the year after the end of its total retention period.
For example:
You have a record that has a total retention period of CY + 10 (that is Current Year + 10 years).
If the record was created in 2003, then CY (Current Year) = 2003.
2003 + 10 years = 2013
That means the Total Retention Period for this record ends at midnight, 31 December 2013 (31/12/2013).
You can destroy this record beginning on 01 January 2014 (01/01/2014), providing it is not relevant to a Document Preservation Notice.
Let's try a few examples:
A record was created in 1999.
It has a Total Retention Period of CY + 9.
When is the last year of that record's total retention period? (Note: Enter the year in YYYY format)
w
Submit
Incorrect. CY+9 refers to the year the record was created plus 9 years. So the last year of the record's Total Retention Period is 2008.
What is the earliest date that the record can be destroyed? (Note: Enter the date in DD/MM/YYYY format)
1999
Submit
Incorrect. The earliest you can destroy the record is January 1, 2009 (01/01/2009).
For example: 01/12/2008 for December 1, 2008
Johnson & Johnson
Click Next to continue.
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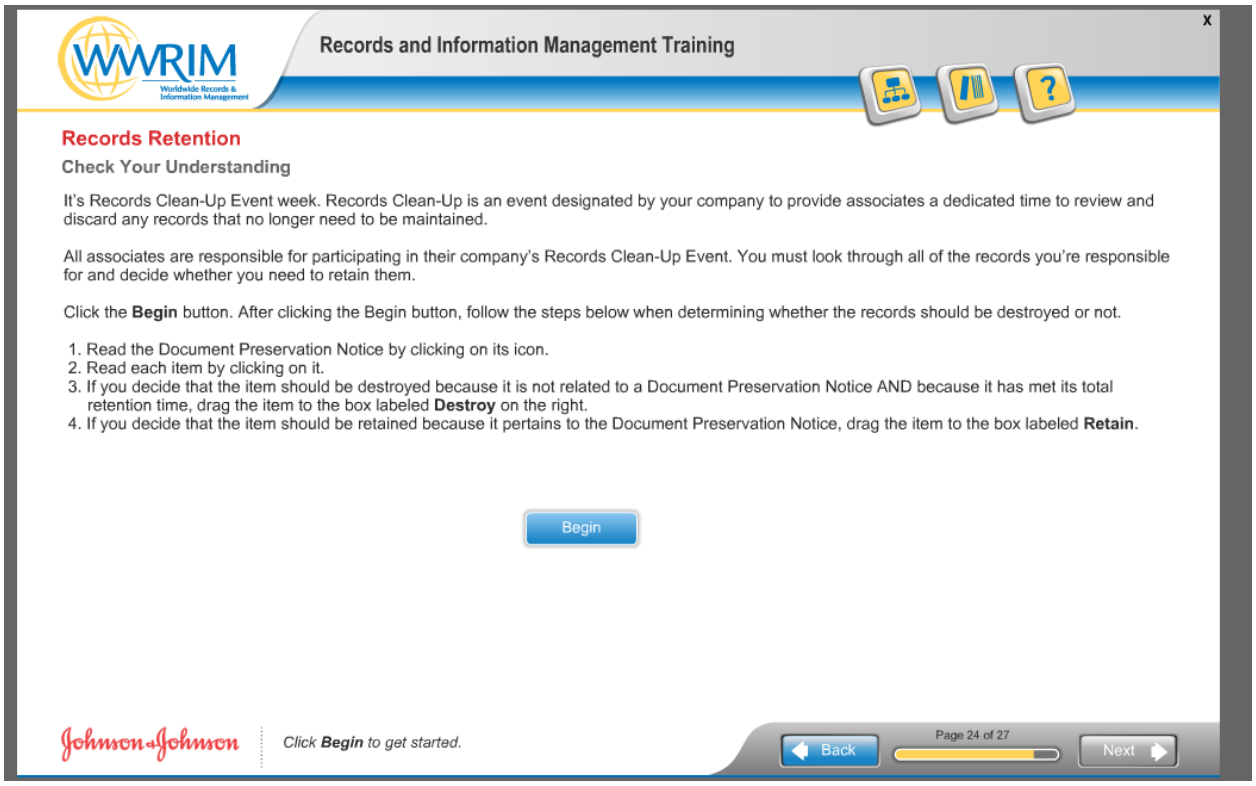
WWRIM
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Records and Information Management Training
Records Retention
Check Your Understanding
It's Records Clean-Up Event week. Records Clean-Up is an event designated by your company to provide associates a dedicated time to review and discard any records that no longer need to be maintained.
All associates are responsible for participating in their company's Records Clean-Up Event. You must look through all of the records you're responsible for and decide whether you need to retain them.
Click the Begin button. After clicking the Begin button, follow the steps below when determining whether the records should be destroyed or not.
1. Read the Document Preservation Notice by clicking on its icon.
2. Read each item by clicking on it.
3. If you decide that the item should be destroyed because it is not related to a Document Preservation Notice AND because it has met its total retention time, drag the item to the box labeled Destroy on the right.
4. If you decide that the item should be retained because it pertains to the Document Preservation Notice, drag the item to the box labeled Retain.
Begin
Johnson & Johnson
Click Begin to get started.
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WWRIM
Worldwide Records & Information Management
Records and Information Management Training
X
Records Retention
Check Your Understanding
Nice job! You don't have to retain this e-mail because it is considered Convenience Information. You may dispose of these types of e-mails after reading them unless they are subject to a Document Preservation Notice.
Retain
Destroy
Staff Meeting Minutes 8-2001 (Word Doc)
Room Change Notification (E-mail)
Instructions
Document Preservation Notice
Records Retention Schedule
Johnson & Johnson
Click Next to continue.
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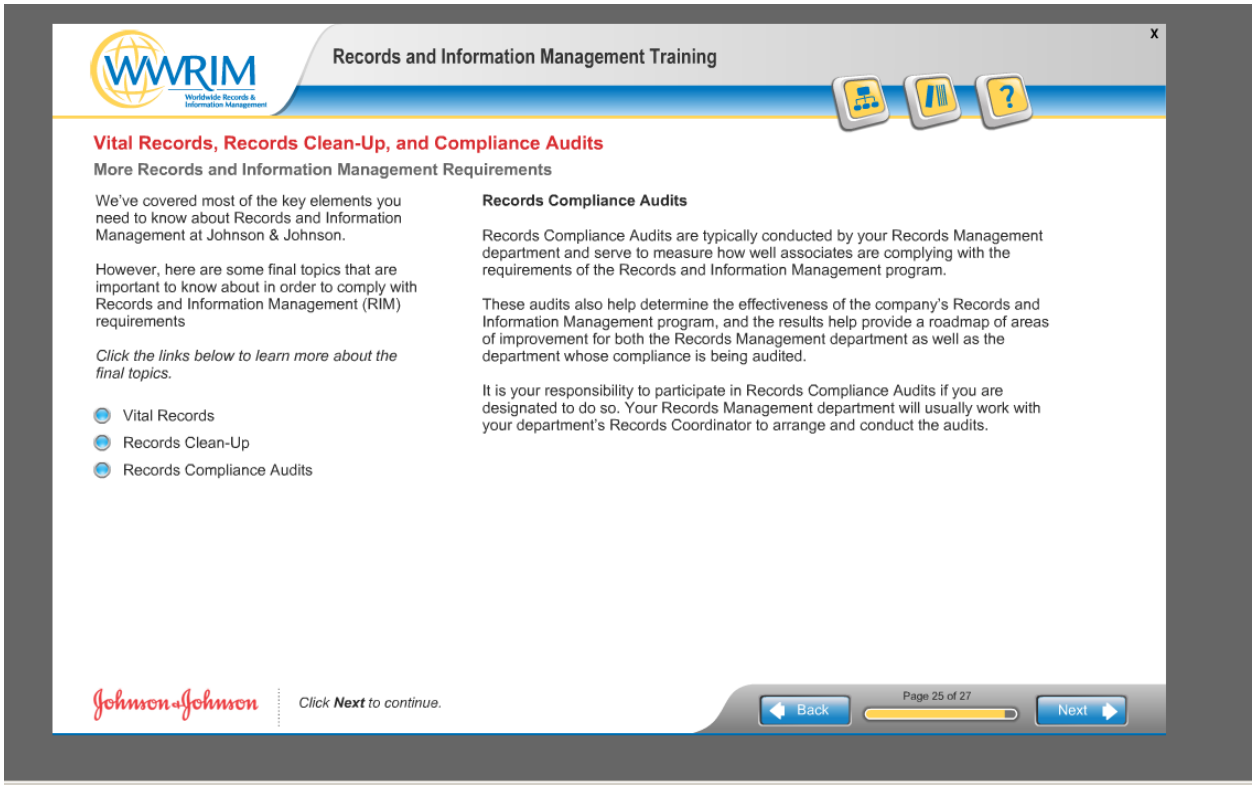
WWRIM
Worldwide Records & Information Management
Records and Information Management Training
x
Vital Records, Records Clean-Up, and Compliance Audits
More Records and Information Management Requirements
We've covered most of the key elements you need to know about Records and Information Management at Johnson & Johnson.
However, here are some final topics that are important to know about in order to comply with Records and Information Management (RIM) requirements
Click the links below to learn more about the final topics.
Vital Records
Records Clean-Up
Records Compliance Audits
Records Compliance Audits
Records Compliance Audits are typically conducted by your Records Management department and serve to measure how well associates are complying with the requirements of the Records and Information Management program.
These audits also help determine the effectiveness of the company's Records and Information Management program, and the results help provide a roadmap of areas of improvement for both the Records Management department as well as the department whose compliance is being audited.
It is your responsibility to participate in Records Compliance Audits if you are designated to do so. Your Records Management department will usually work with your department's Records Coordinator to arrange and conduct the audits.
Johnson & Johnson
Click Next to continue.
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WWRIM
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Records and Information Management Training
x
Vital Records, Records Clean-Up, and Compliance Audits
Check Your Understanding
Sorry! You have not matched the options with the descriptions correctly.
Option
Description
Vital Records
Fundamental to the functioning of an organization and necessary to continue operations without delay under abnormal conditions.
Records Clean-Up Events
Opportunity and time allotted to review your records against the Retention Schedule and the Document Preservation Notices and participate in the controlled destruction of eligible records.
Records Compliance Audits
Help gauge how well associates are complying with the requirements of the Records and Information Management program.
Johnson & Johnson
Click Next to continue.
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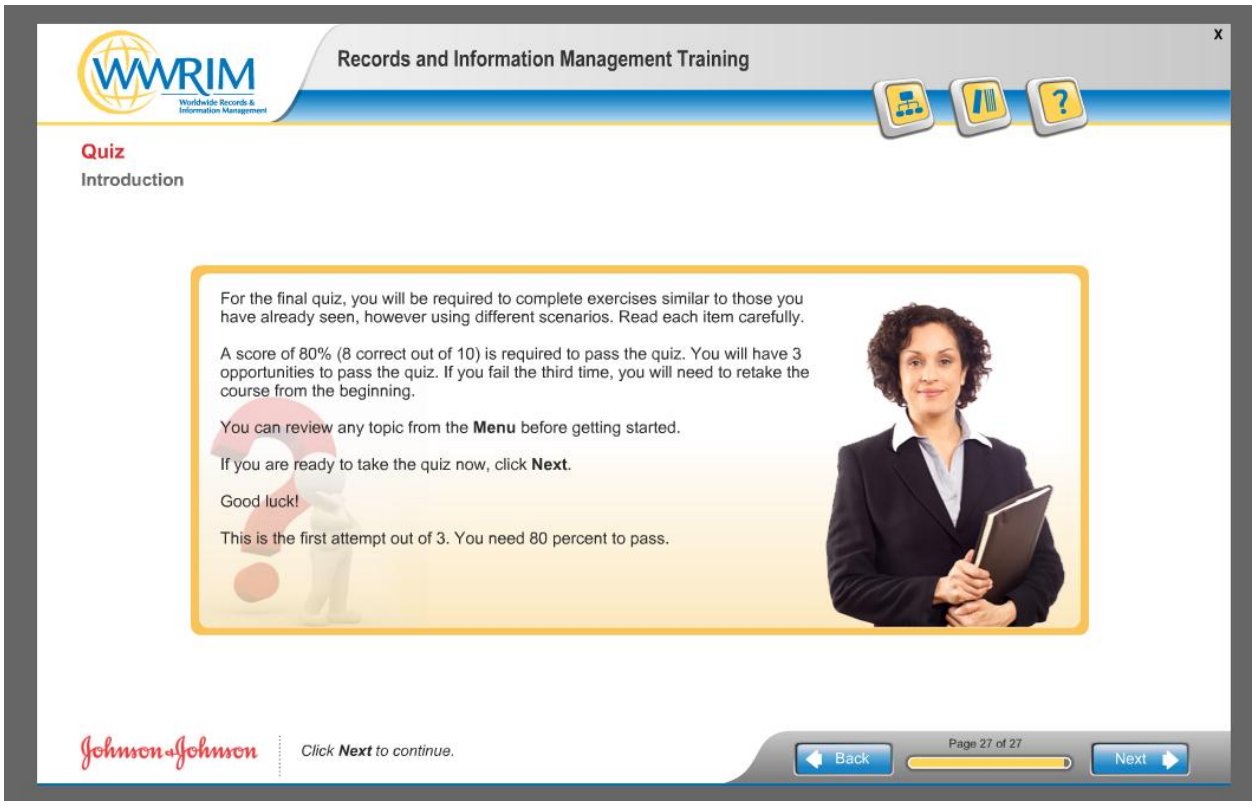
WWRIM
Worldwide Records & Information Management
Records and Information Management Training
x
Quiz
Introduction
For the final quiz, you will be required to complete exercises similar to those you have already seen, however using different scenarios. Read each item carefully.
A score of 80% (8 correct out of 10) is required to pass the quiz. You will have 3 opportunities to pass the quiz. If you fail the third time, you will need to retake the course from the beginning.
You can review any topic from the Menu before getting started.
If you are ready to take the quiz now, click Next.
Good luck!
This is the first attempt out of 3. You need 80 percent to pass.
Johnson & Johnson
Click Next to continue.
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Exhibit B

ETHICON INC.
a Johnson & Johnson company

Document Name (#): PR553-003
Revision: 12

COMPANY PROCEDURE FOR TRANSFERRING / TERMINATING EMPLOYEES AND CONTRACTORS

REVISION HISTORY FOR PR553-003

Revision #	Summary of Change	Change Order #	Originator
12	Added Mentor Santa Barbara to the Section 2: Scope. Updated Employee / Contractor Role in Section 4: Roles and Responsibilities. Changed references to the Ethicon Change Control System (ECCS) to Document Control System. Updated Appendix I references of the Litigation Vault to Litigation Hold folder. Updated Appendix I Items #1 & 18 in order to align with changes released by Johnson & Johnson Corporate Worldwide Records & Information Management to RIMS-5 Inactive Records & Information Storage Standard and RIMS-9 *Management of Records and Information of Departing Associates Standard*.	CO-0036329	W. Patire-Singer
11	Major re-write to improve clarity to the end users & to better align to the new J&J Corporate Worldwide Records & Information (WWRIM) Management of Records and Information of Departing Associates Standard (RIMS-9). Form & Certification have also been modified to be completed electronically rather than manually.	CO-0029899	W. Patire-Singer
10	Revised to edit the Scope section. Add Guaynabo departments for implementation.	CO-0024320	W. Patire-Singer

1. PURPOSE

This procedure describes the process by which all employees or contractors who leave ETHICON are required to review all of their paper and electronic records, prior to their departure. In order to manage the Records and Information, departing employees and/or contractors need to assure that their records and information are reviewed and dispositioned in compliance with the ETHICON Records Retention Schedule (RRS), and active Preservation Hold Notices.

2. SCOPE

This process applies to the following ETHICON locations:

- Cornelia, Georgia
- Guaynabo, Puerto Rico
- Juarez, Mexico
- Raleigh, North Carolina
- San Angelo, Texas
- San Lorenzo, Puerto Rico
- Santa Barbara, California
- Somerville, New Jersey

3. DEFINITIONS, ACRONYMS AND ABBREVIATIONS

Reference terms used in this document are found in PS-0000971 *Franchise Process Specification for the Records Management Program Glossary.*

4. ROLES AND RESPONSIBILITIES

Roles and Responsibilities	Description
Human Resources Vice President	Provide the necessary guidelines and instructions for terminated/transferred employees & contractors via the ETHICON Exit Processes. Transfer HR files to other J&J Human Resources Departments as employee transfer situations occur. Work with ComplianceWire Administrators to facilitate consistent training on this document for Site Records Management staff, Records Coordinators, and Managers/Supervisors and any other site specific relevant targeted training audience. Adjust this procedure and/or provide feedback on any areas of process to respond to changing business needs.

Roles and Responsibilities	Description
Manager/ Supervisor (includes District/ Divisional Managers)	Ensure that: 1) Records of all departing direct reporting individuals are dispositioned appropriately per established Company Procedures, active Preservation Hold Notices and per the requirements of this Procedure & Certification. 2) The terminating or transferring individual fully understands how to review and disposition their records, where to locate the Records Retention Schedule, Preservation Hold Notices and other relevant Record Review and Disposition related Documents. 3) Instruct IT that the departing individual's records need to be taken off of the computer and put on a CD or equivalent technology within 30 days when an individual is unable to perform their own records disposition prior to their departure to avoid their files being re-imaged prior to dispositioning the records. Manager/Supervisor then is responsible for performing the records review & disposition.
Employee / Contractor (Consultant/Contractor Kelly Temp, or other Temporary Workers)	Work with their Manager to complete the Exit Checklist & Certificate of Compliance For Records Disposition (APPENDIX I) prior to exiting ETHICON in order to clean-up and appropriately disposition their records per established Company Procedures and active Preservation Hold Notices. If the temporary worker is unable to do this prior to their departure (e.g. if the departure is short notice), then it is the responsibility of the Manager/Supervisor to whom this person reported to disposition their records and disconnect their system/security authorizations. The departing employee or contractor may take with them upon departure any personal notes provided these documents, in their entirety, were (1) not prepared, used for, or communicated in the course of transacting Ethicon business, and (2) not subject to an active Preservation Hold Notice for any reason.
ITS Representatives	Obtaining the terminating/transferring employee's or contractor's /consultant's computer files and provide a CD of the individual's files if required by their Manager/Supervisor. Ensuring that computer Accounts are disabled within 30 days and that files are removed within 90 days.

5. MINIMUM REQUIREMENTS

The Manager and Employee / Contractor must follow & complete the process outlined in **Appendix I**.

6. APPENDICES

Appendix	Appendix Name
Appendix I	Transferring/ Terminating Employee / Contractor Checklist & "Certificate of Compliance for Records & Information Disposition"

APPENDIX I: TRANSFERRING / TERMINATING EMPLOYEE / CONTRACTOR CHECKLIST & "CERTIFICATE OF COMPLIANCE FOR RECORDS & INFORMATION DISPOSITION"

Management's Responsibility PRIOR to the Employee/Contractor leaving the company:

☐ 1. Instruct employee/contractor to review his or her paper and electronic files against approved records retention schedules, and any Preservation Notices in effect in order to be sure they understand where and how to find and follow the Records Retention Schedule and Preservation Hold Notices in order to perform their records review. **The 4 types of Litigation are: Employment, Product, Patent and General Litigation.** The link to the Johnson & Johnson Legal Hold Notice Site is available on the ETHICON Records Management Intranet Portal and on the ETHICON Somerville Human Resources Exit Process Portal. Any records, paper or electronic, that are under litigation, must be labeled (Case name of Litigation) and forwarded to their manager.

All electronic Outlook Software records (Word, Excel, PowerPoint, Access, etc.) must be moved to the Litigation Hold folder on your desktop per the instructions in the respective, relevant Preservation Hold Notices. Move electronic files subject to Preservation Hold Notices to the Litigation Hold as follows:

- **Paper Records-**

  All paper records that are under litigation should be flagged and forwarded to your immediate manager.

- **Electronic Records**-

  All electronic email records must be moved to the Litigation Hold folder in your Microsoft Outlook Inbox per the instructions in the respective relevant Preservation Hold Notices.

  All electronic Outlook Software records (Word, Excel, PowerPoint, Access, etc.) must be moved to the Litigation Hold folder on your desktop per the instructions in the respective, relevant Preservation Hold Notices.

- Ensure employee/contractor references PS-0000117 – *Process Specification for Onsite Paper/Electronic Records Clean-up*. Follow all instructions in PS-0000117 including completion of the electronic records clean-up tracker. These can be found in the Document Control System or on the Records Management Intranet portal.
- Records and information determined to be eligible for destruction or deletion after this review process shall be:
  - Destroyed at that time in accordance with ETHICON Procedures OR
  - Transferred to the Supervisor to retain until ETHICON's annually scheduled Records Clean-up event, at which point those records will be re-reviewed, re-dispositioned and destroyed, as appropriate. OR
  - Destroyed/deleted at that time with written approval by the supervisor.
- Once the employee/contractor has completed their paper and electronic review of all records, then instruct the individual to transfer the remaining records to management or their management representative.

NOTE: Do not move email and files from C, H, and other drives to department shared drives for permanent storage.

☐ 2. If the employee/contractor has staff reporting to them, then instruct that all department staff's personnel files are transferred to the newly appointed manager.

☐ 3. The individual's supervisor will ensure, commensurate with the risk, that all appropriate passwords are changed immediately. If a resigning/ transferring/ terminated employee or contractor is responsible for the system (application) administration of ANY ETHICON System (application), then the individual's supervisor is responsible for ensuring the individual's:

- System Administrator Rights need to be deleted immediately for each system to which they have System Administrator rights.
- Password(s) is/are changed immediately.

☐ 4. If the employee/contractor has access to Document Control System, then instruct the individual to transfer all pending document change packages to another permanent individual with the required Document Control System role or request that they cancel the change packages. Contact WW Quality Systems or your local Quality System associate for assistance if required.

- If the employee is identified as a Document Owner, then a new document owner must be identified and the required forms be completed. Refer to PR-0000001, Company Procedure for the ETHICON Document Management Process, for details. Complete FM-0000001, Document Control System Document Ownership Transfer Form, and process per instructions.
- If the employee is a Document Control System Approver, then they must ensure that an alternate approver is identified for them. If the employee functions in the role of Document Control System Implementer, they must ensure the Implementer role is transferred to an appropriate associate within their functional group.

☐ 5. If the employee/contractor has access to the Corrective and Preventative Action (CAPA) System, then instruct the individual to take the necessary steps to transfer the CAPA ownership of all **pending** CAPA's to another individual to be identified by the Manager.

If the employee is in the Approver role in CAPA, they must ensure that all pending approvals are executed prior to termination or take steps to transfer the approval responsibility to another appropriate approver in the CAPA System.

☐ 6. If the employee/contractor has access to the Non-Conformance Report (NCR) System, then instruct the individual to work with the NCR Site Leader to transfer all pending NCR's under his/her name as an NCR Owner and/or Product Control Owner to another individual with the required NCR role.

If the employee is identified as having an Approver Role in the NCR System, then ensure all the NCR's pending his/her approval are identified and reassigned by the NCR Site Leader.

☐ 7. **For Field Sales Management Only:** If your field based employee did not complete the records clean-up and did not sign the Certificate of Compliance prior to departure, then the Field Service Equipment Vendor will copy the electronic records on to a CD and send a copy to the District Manager or Management Representative for review and disposition in accordance with this policy. Utilize the Field Sales Equipment vendor to obtain the terminated/ transferred field sales employee's laptop or any other company assets that were issued to the individual back to C3I.

☐ 8. **For United States Based Human Resources Employees / Contractors Only:** No Human Resources related records can be deleted or discarded. Manager needs to send the computers to the **Global Site Services Lead** so a copy of the hard drives can be made before the computer can be re-imaged. This process step is required in order to support the Gutierrez, Morgan, Brown & Marshall v. Johnson & Johnson Employment Litigation Case.

☐ 9. Forward the employee's personnel file to the Human Resource Department if the employee is leaving or transferring to another J&J Company. If the employee is transferring to another department within ETHICON, forward the personnel file to the new manager.

- All Contractor department files remain in the department and should **not** be sent to Human Resources. These files are to be retained per the "Consultant/Contractor Contract & Supportive Documentation" Record Title on the Administrative Records Retention Schedule.

- **UNTIL FURTHER NOTICE, ALL PERSONNEL FILES, INCLUDING COMPENSATION INFORMATION ARE UNDER PRESERVATION HOLD - DO NOT DESTROY OR REMOVE DOCUMENTS FROM THE FILE.**

☐ 10. The employee/contractor is required to return all ETHICON owned software, and equipment upon the end of employment.

☐ 11. If any records were password protected, then the passwords should be communicated to their Manager before leaving.

☐ 12. Manager is to identify if the employee/contractor is an authorized user for a contracted offsite Records Storage Vendor for the retrieval of offsite records such as Iron Mountain, Angelo Archives, etc. If yes, then the manager must notify Site Records Manager that the individual is leaving the company and must be removed from the Contracted Offsite Records Storage Vendor authorization list. Has the employee/contractor retrieved any records from the offsite facility? If yes, then instruct the individual to identify & document the location of those records (boxes).

☐ 13. Instruct employee/contractor to return laboratory notebooks to Managers.

☐ 14. Instruct employee/contractor to identify any company paid services that they subscribe to. The Manager must remove the individual from the respective subscription(s).

☐ 15. Remove employee's/contractor's name from any distribution lists.

☐ 16. A (Service Request Management) SRM Form must be completed to request the following:

- Delete inactive accounts such as NT id, Mailbox and specific applications with user access.
- Identify if the employee/contractor has access to any other SharePoint Sites, shared drive systems, etc. If so, manager should request removal from those respective lists and group shares.
- Coordinate the pick-up all ETHICON equipment such as laptop, blackberry, printer, etc. that is in the possession of the departing or transferring individual.

☐ 17. Manager/Supervisor of terminated/transferring employee/contractor must complete the Certificate of Compliance Form for Records Disposition to certify that the individual's records have been reviewed and that proper disposition has been determined within 30 day. (**Appendix I**). Submit or retain the completed Certificate of Compliance Form for Records Disposition as it instructs based upon whether the individual is an employee or a contractor.

- **For the Employee:** The original Certificate of Compliance must be filed in the Employee's Personnel File along with the Exit Checklist and forwarded to Human Resources.
- **For the Temporary Assignment Employee transferring back to their original J&J Operating Company location:** The original completed Certificate of Compliance is retained in the Human Resources file of the ETHICON site where the Associate worked on temporary assignment.
- **For the Consultant:** The completed Certificate of Compliance is retained in the consultant/contractor Department file. This will remain in the department for the applicable Retention Period on the current approved Records Retention Schedule.

☐ 18. In the event the employee/contractor does not complete these steps before leaving, their management or their management representative must, within 30 days after the individual has left the company:

- Assume responsibility for this review, transfer and disposition procedure.
- Request that IT create a copy of the Associate's electronic records on to a CD-Rom via an SRM request for the CD-Rom to be forwarded to them promptly for disposition.

☐ 19. If the departing employee / contractor served as a Records Coordinator or a Department Head, then notify the Site Records Manager of this individual's departure and who their replacement will be who will assume these responsibilities for the Department moving forward.

ETHICON INC.
a Johnson & Johnson company

Document Name (#): PR553-003
Revision: 12

ETHICON TRANSFERRING / TERMINATING EMPLOYEE / CONTRACTOR

CERTIFICATE OF COMPLIANCE FORM FOR RECORDS DISPOSITION

NAME OF EMPLOYEE OR CONTRACTOR: _____
(PRINT Name)

Employment Status: ***(Check One)*** ☐ Employee ☐ Contractor

Division Worked In: _____
(Check One)
- ☐ Non-Human Resources Employee
- ☐ Human Resources Employee (None of their files can be destroyed or dispositioned.)

Departure Reason: ***(Check One)***
- ☐ Transfer to another Johnson & Johnson Operating Company
- ☐ Transfer to another ETHICON Site/Division
- ☐ Employment Termination
- ☐ Contract Expiration
- ☐ Contract Termination

Termination Circumstance: ***(Check One)***
- ☐ Voluntary Departure
- ☐ Non-Voluntary Departure

CERTIFICATION:

I hereby confirm that, to the best of my knowledge, all paper & electronic records owned by _____ have been reviewed and subsequently either dispersed and/or
(Name of Employee / Contractor)
disposed of per the requirements of:

- PS-0000117 ETHICON Onsite Paper / Electronic Records Clean-up
- PR-0000018 ETHICON Records Retention Schedule
- Active Preservation Hold Notices for Product, General, Employment and Patent related litigations

_____	_____	_____
PRINT MANAGER'S NAME	*MANAGER'S SIGNATURE*	*DATE*

ROUTING INSTRUCTIONS:
- For Terminating Employees: Include this completed & signed document in the Employee's Personnel File and forward with the completed Exit Checklist to Human Resources.
- For Transferring Employees: The individual's personnel file transfers to either the new department or to the HR Department on behalf of the terminating or transferring employee.
- For Contractors: Retain this completed & signed document in the Contractor's Department file. This will remain in the department for the applicable Retention Period per the requirement listed on the approved Company Records Retention Schedule.

Exhibit C

From: Meek, Andrew [ETHUS] <AMeek@ETHUS.JNJ.com>
Sent: Fri, 31 Aug 2007 15:13:14 GMT
To: DL-ETHUSSO EWHU DMs <DL-ETHUSSOSLSSPECIALTYDMs@ETHUS.JNJ.com>; Pattyson, Bart [ETHUS] <BPATTYSON@ETHUS.JNJ.com>; Gatewood, Jim [ETHUS] <JGatewoo2@ETHUS.JNJ.com>; Zipfel, Robert [ETHUS] <RZipfel@ETHUS.JNJ.com>; Yu, Kyung [ETHUS] <KYu@ETHUS.JNJ.com>; Parisi, Paul [ETHUS] <PParisi@ETHUS.JNJ.com>; St. Hilaire, Price [ETHUS] <PSTHILAI@ETHUS.JNJ.com>; Barendse, Stevan [ETHUS] <SBarends@ETHUS.JNJ.com>; Meek, Andrew [ETHUS] <AMeek@ETHUS.JNJ.com>
Subject: Nov 3 Cadaver Lab - Dallas, TX

DMs/RSDs,
Please forward to you teams.

I am excited to announce the debut of a new course on November 3 in Dallas, TX - Advanced Pelvic Floor Course - Level 1. The surgeon targets for this course are plicators, biologic users, flat mesh users with little experience, etc.

The goal for this lab is to train these doctors to prepare them for using mesh for pelvic floor repairs. The content that will be covered is as follows:

1. Pelvic Floor Anatomy, to include anatomic dissection
2. Diagnosis of pelvic floor defects, levels of support, staging
3. Graft selection criteria for augmented repairs
4. Graft implantation techniques
5. Handling complications

The cadaver lab will focus on anatomy, dissection, and placement of GYNEMESH.
Again, the targets for this course are surgeons with little or no experience using mesh with pelvic floor repairs. The experience gained at this level 1 course will prepare these doctors to possibly take a level 2 course in the future, which will feature Prolift.
This course is fully funded and will not impact region/division PE budgets. It is open to all regions. The course is posted on-line and the brochure is attached. Good luck!

Andy

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Exhibit D

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Sent: Fri, 06 Apr 2012 14:52:05 GMT
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Subject: POP/INC BRAND TEAM CALL - Minutes from 4/5/2012

INCONTINENCE & PELVIC ORGAN PROLAPSE BRAND TEAM,

Thank you to those of you who were able to make yesterday's call, including: Troy Mohler, Ed Stewart, Garrin Rose, JD Sovereign, Stephanie Garbarino, and the marketing team. I realize that there was a last minute change to when this call was being held and that people had trouble with the dial-in number…

For those of you who were not able to make the call we covered three topics:

1) EARL-

a) Likes – The team is generally happy with the content that is available on EARL and are finding it useful in their selling efforts

b) Improvements - The team had a few recommendations for improvements to the content including:

i) Update all Price Quotes (currently on the Portal) to 2012 pricing and make available on EARL

ii)Enable the animated TVT procedure videos to be emailable to customers (last 3 video assets under TVT ABBREVO)

iii) Add an emailable letter to the POP brands that provides customers with an update on the FDA and regulatory issues (currently only available as an Internal FAQ)

iv) Add all Patient marketing materials to EARL (vs having on portal)

2) Sales and Marketing Portal

a) The team felt that the Portal was out of date and only used it 1 time / month on average

i) e.g. Price Quotes currently on the portal are for 2011 in some cases…

b) The Portal is currently being redesigned to focus primarily on INTERNAL Only materials while EARL will be our primary venue for materials that are customer facing.

c) It was noted that any presentation or document on the Portal can be uploaded to EARL by first saving it as a PDF, then emailing it to yourself, then opening on your iPad and storing it under iBOOKS, however it

would be nice if we could simplify this and just make certain documents (like Price Quotes) available on the Ipad.

c) Now that reps have EARL, they often will call on customers without their laptops so having everything they need on the ipad makes them more efficient

3) Y-mesh Launch

a) We are getting close to being able to share specific launch information with the organization!

b) In the meantime, we discussed some recommended actions that ALL reps can do NOW, in order to prepare for and maximize the launch:

i) We discussed how familiar most reps are with the sacrocolpopexy procedure. Most people thought that reps could benefit now by being in a few cases and asking questions and really understanding the procedures. Given that GYNECARE TVT and GYNECARE MORCELLEX are sometimes used in the same patients (concomitantly) as a Y-mesh this is something every rep can do now without detracting from the focus.

ii) Although not discussed on the call, here is some additional information that comes from one of the reps on our Y-mesh launch team:

Recommendation is to talk with the GYN/URO who sits on the Value Analysis Committees in your Key Accounts. Make sure you understand the procedure for introducing new products in these facilities. Understand and get copies of the forms are required to be completed, so that when you speak to your competitive y-mesh surgeons for the first time you have the new product request form in hand. Sometimes the surgeons will be willing to sign and fill out the forms right on the spot. **The rep will not speak about the Y mesh at all at this time**. They just need to understand the process and get the appropriate forms. The process should be the same for any product.

Brian Luscombe
US Product Director, Pelvic Reconstructive Surgery

http://teamsna.jnj.com/eth/projecttomorrow/Shared%20Documents/ProjectTomor

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